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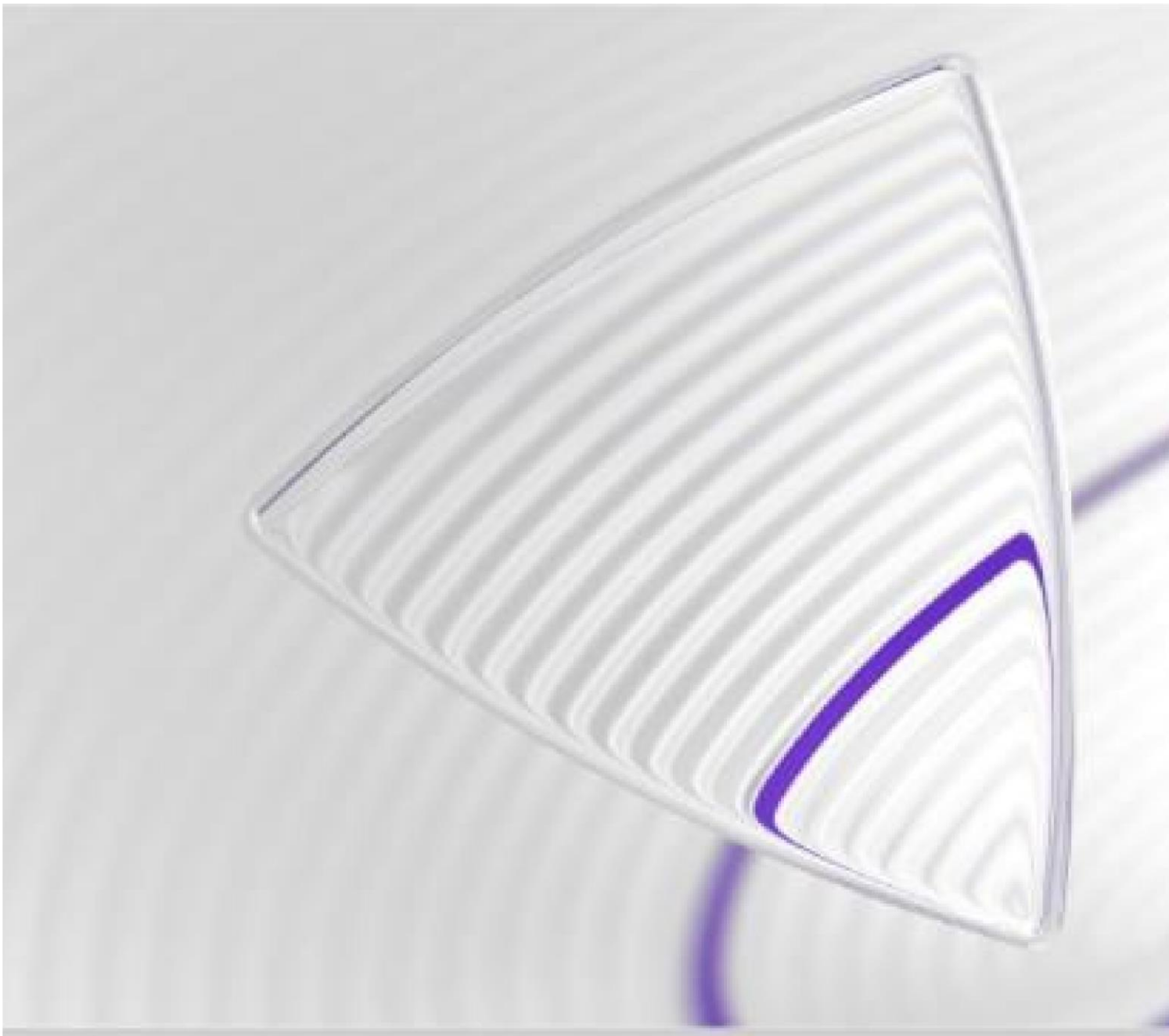
藥物檢索報告

奈米藥物載體於抗腫瘤及 COVID-19 應用之市場分析

Prepared For: Taipei Medical University (臺北醫學大學)

Feb 10, 2022



Cortellis

Drug Report

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1. NVX-CoV2373
2. paclitaxel (albumin-bound, breast cancer), Hunan Kelun Pharmaceutical
3. abiraterone acetate (oral nanoparticle formulation/SoluMatrix, prostate cancer), iCeutica/Sun Pharmaceutical
4. doxorubicin (intravenous nanosomal lipid suspension/Nanoaqualip, cancer), Jina Pharmaceuticals/Intas Pharmaceuticals
5. doxorubicin (XR-17 encapsulated, cancer), Oasmia

Created: 10-Feb-2022

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NVX-CoV2373

SNAPSHOT

Drug Name	NVX-CoV2373
Other Drug Names	COVID-19, Novavax; coronavirus COVID-19 infection (protein subunit vaccine, Matrix-M), Novavax; SARS-CoV-2 protein subunit vaccine (nanoparticles, COVID-19), Novavax; NVX-CoV2373; SARS-CoV-2 rS; TAK-019; Covovax; COVID-19 Beta (B.1.351) variant strain vaccine; rS-B.1.351; NVX-CoV2372; Recombinant Spike Protein of SARS-CoV-2 Virus; Nuvaxovid
Originator Company	Novavax Inc
Active Companies	Novavax Inc; Serum Institute of India Ltd; Takeda Pharmaceutical Co Ltd; SK Bioscience
Therapy Area	Infection
Inactive Companies	
Highest Status	Registered
Regulatory Designations	Emergency Use Authorization; Fast Track
Active Indications	Coronavirus disease 19 infection
Inactive Indications	
Target-based Actions	COVID19 Spike glycoprotein modulator
Other Actions	Protein subunit vaccine; Prophylactic vaccine; Adjuvant
Technologies	Nanoparticle formulation injectable; Intramuscular formulation; Biological therapeutic; Protein recombinant; Liquid formulation
Franchises	COVID-19
EphMRA Codes	
Last Change Date	13-Feb-2022
Added Date	03-Mar-2020

DEVELOPMENT PROFILE

SUMMARY

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Novavax, in collaboration with Serum Institute of India and Japanese licensee Takeda Pharmaceutical, has developed NVX-CoV2373 (NVX-CoV2372; Covovax; Recombinant Spike Protein of SARS-CoV-2 Virus; Nuvaxovid; TAK-019), a vaccine comprising antigens derived from SARS-CoV-2 spike (S) protein, developed using company's recombinant protein nanoparticle technology platform, along with the saponin-based adjuvant Matrix-M [2249020], [2307374], [2307567], [2506183]. In the EU the vaccine is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older [2590070].

In November 2021, the vaccine received emergency use authorization (EUA) in its first region in Indonesia; Serum Institute of India was to market the vaccine and shipments were to begin imminently [2557909], [2559413]. In December 2021, the vaccine was approved in the EU [2586804]. In February 2021, a rolling review process was initiated with the US FDA [2402631], [2451131]; in December 2021, Novavax completed submission of the final data package for EUA of the vaccine in the US; a request for EUA was to be filed within 1 month [2590782]. In December 2021, an NDA for the vaccine was submitted in Japan; distribution was to begin in early 2022, pending approval [2584695], [2586721]. In December 2021, the World Health Organization (WHO) granted Emergency Use Listing (EUL) for NVX-CoV2373, as manufactured and marketed by Serum Institute of India as Covovax, and as marketed by Novavax as Nuvaxovid [2585991], [2587020].

In November 2021, the company expected to have a regulatory package for global submission in pediatric patients available in 1Q22, based on the pediatric expansion of the PREVENT-19 trial [2560964].

In December 2021, an extension of the PREVENT-19 trial to assess booster (third) doses of the vaccine was initiated [2588012].

The company is also investigating a combined influenza/corona virus vaccine with NanoFlu and NVX-CoV2373 for post-pandemic use [2340857].

In January 2021, development of new constructs against the emerging strains was initiated and an ideal candidates for a booster or combination bivalent vaccine for the new strain was expected to be selected in the coming days . At the same time, clinical testing of new vaccines was planned to initiate in 2Q21 [2398778]. In May 2021, a phase II trial (COVID-19 vaccine booster trial) was planned to begin in the UK in the first week of June [2460423]. In June 2021, positive data on the ability of sera isolated from individuals who had participated in a phase II clinical trial and who had received a second dose of the vaccine to neutralize the Alpha (B.1.1.7) and Beta (B.1.351) strains were reported; at that time, further clinical testing of rS-B.1.351 was planned to begin by December 2021 [2475222].

REGULATORY

In November 2021, the company expected to have a regulatory package for global submission in pediatric patients available in 1Q22, based on the pediatric expansion of the PREVENT-19 trial [2560964].

In August 2021, a filing for WHO EUL was expected later that month [2506188]. in September 2021, Novavax and Serum Institute of India filed a regulatory submission for the WHO EUL of NVX-CoV2373, a prerequisite for exporting the vaccine to participating countries [2534981]. In October 2021, completion of the regulatory filing with the WHO was expected ‘shortly’ [2556077]. In November 2021, Novavax completed its rolling submission for EUL with the WHO to prevent COVID-19 [2561155]. In December 2021, the World Health Organization (WHO) granted Emergency Use Listing (EUL) for NVX-CoV2373, as manufactured and marketed by Serum Institute of India as Covovax, and as marketed by Novavax as Nuvaxovid [2585991], [2587020].

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In May 2021, Novavax entered into an Advance Purchase Agreement with Gavi the Vaccine Alliance (Gavi) for manufacturing and supply of COVID-19 vaccine to the countries participating under COVAX Facility. Under the APA, Novavax was expected to manufacture and distribute 350 million doses of NVX-CoV2373. Under a separate purchase agreement with Gavi, the Serum Institute of India (Serum Institute) was expected to manufacture and deliver the balance of the 1.1 billion doses of Novavax vaccine in 3Q21 [2449093].

In June 2020, Novavax was planning to launch 100 million doses by the end of 2020 [2287239].

THE US

In August 2020, Novavax expected filing for approval of the vaccine in the US in December 2020 [2312250]. In November 2020, the US FDA granted Fast Track Designation for NVX-CoV2373 for the prevention of SARS-CoV-2 infection (COVID-19) [2358543]. In February 2021, a rolling review process was initiated with the US FDA [2402631]. In May 2021, Novavax planned to complete the rolling submission in the coming months and file for authorization with the FDA in 3Q21 [2451131]. In August 2021 a US filing for emergency use authorization was expected in 4Q21 [2506188]. In October 2021, Novavax expected to complete the rolling submission in the US by the end of 2021 [2556077]. In December 2021, Novavax completed submission of the final data package for emergency use authorization (EUA) of the vaccine in the US; a request for EUA was to be filed within 1 month [2590782].

EUROPE

In August 2021, the EC agreed to purchase 100 million doses of the vaccine with an option to acquire an additional 100 million doses through 2023 [2504992].

In February 2021, Novavax announced an agreement for Switzerland to purchase 6 million doses of NVX-CoV2373 [2401922], [2440361].

In February 2021, a rolling review process was initiated with the EMA [2402631]. In May 2021, Novavax planned to complete the rolling submission in the coming months and file for authorization with the EMA in 3Q21 [2451131]; In August 2021, the filing was expected to complete within weeks of a completed UK MHRA filing, which was expected in 3Q21 [2506188]. In October 2021, completion of the regulatory filing with the EMA was expected ‘shortly’ [2556077]. In November 2021, Novavax completed the submission of all data modules to the EMA to support the final regulatory review of its dossier [2557904]. Later that month, the EMA begun the review of the filing for CMA and a decision was possible within weeks; the product would be marketed as Nuvaxovid [2569471], [2569757]. In December 2021, the CHMP of the EMA recommended approval of the vaccine to prevent COVID-19 in people from 18 years of age and older [2586642], [2586528]; later in December 2021, the vaccine was approved in the EU [2586804].

In mid-January 2021, a rolling filing was initiated in the UK with the MHRA [2398778]. In May 2021, Novavax planned to complete the rolling submissions in the coming months and file for authorization with the MHRA in 3Q21 [2451131]; in August 2021, this remained the case [2506188]. In October 2021, the rolling regulatory submission was completed in the UK for CMA for the prevention of SARS-CoV-2 infection (COVID-19); the submission included data from the pivotal phase III 2019nCoV-302 study and from the PREVENT-19 study [2556077]. By December 2021, an agreement had presumably been made in the UK for 60 million doses of the vaccine [2576405].

JAPAN

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In September 2021, Takeda agreed to manufacture and supply 150 million doses of the vaccine to the Government of Japan. At that time, the company expected to manufacture more than 250 million vaccine doses per year [2523158], [2526227].

In August 2020, licensee Takeda Pharmaceutical would be responsible for regulatory submissions to the Japan's Ministry of Health, Labour and Welfare (MHLW) and would produce and distribute TAK-019 in Japan [2307567]. In February 2021, Takeda intended to start distributing TAK-019 in late 2021 [2411374]. In May 2021, distribution was expected to begin in late 2021 or early 2022 and would continue into 2022 onwards [2450474]. At that time, approval was expected in fiscal year 2021 [2451427]. In September 2021, distribution was to begin in early 2022 [2523158], [2526227]. In December 2021, an NDA for the vaccine was submitted in Japan; distribution was to begin in early 2022, pending approval [2584695], [2586721].

REST OF THE WORLD

CANADA

In February 2021, rolling review process was initiated with Health Canada [2402631]. Later that month, the company agreed to supply up to 76 million doses of vaccine to Canada [2413428]. In August 2021, the filing in Canada was expected to complete within weeks of a completed UK MHRA filing, which was expected in 3Q21 [2506188]. In October 2021, completion of the regulatory filing was expected ‘shortly’ [2556077]. In November 2021, the rolling submission to Health Canada was completed. The filing was based on data from the PREVENT-19 trial [2557904].

MIDDLE EAST AND AFRICA

In January 2022, Novavax and Israel's Ministry of Health entered into an advance purchase agreement for an initial 5 million doses of the vaccine, with an option to purchase an additional 5 million doses [2605647].

In January 2022, the vaccine was filed for emergency use authorization in South Africa [2595305].

In December 2021, an emergency use filing was submitted in the United Arab Emirates [2580945].

SOUTH ASIA

In August 2020, licensee Serum Institute would be responsible for regulatory submissions and marketing authorizations in low- and middle-income countries (LMIC) and India [2307374]. In August 2021, a regulatory filing for emergency use authorization was submitted to the Drugs Controller General of India (DCGI) [2506182]. By November 2021, the submission was completed [2560964]. In December 2021, the vaccine was granted emergency use authorization (EUA) in India [2589837].

ASIA PACIFIC

In November 2021, a filing was submitted to the Singapore Health Sciences Authority for interim authorization, presumably EUA, of the vaccine under the Pandemic Special Access Route [2572763].

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In August 2021, a regulatory filing for emergency use authorization was submitted in Indonesia [2506182]. In November 2021, the vaccine, as Covovax, received emergency use authorization in its first region in Indonesia; Serum Institute of India was to market the vaccine and shipments were to begin imminently [2557909], [2559413].

In August 2021, a regulatory filing for emergency use authorization was submitted in the Philippines [2506182]. By November 2021, the submission was completed [2560964]. In November 2021, the vaccine, as Covovax, received emergency use authorization in the Philippines; Serum Institute of India was to market the vaccine [2569374].

In April 2021, licensee SK Bioscience filed for a rolling review of the Novavax COVID-19 vaccine in South Korea [2446922]. In November 2021, submission of the BLA was completed. By that time, SK Biosciences had finalized an advance purchase agreement with the Korean government for the supply of 40 million doses to South Korea. SK Biosciences expected to make the product available immediately after receiving approval [2566959], [2568295]. In January 2022, the vaccine was approved in South Korea for active immunization in individuals 18 years of age and older for the prevention of COVID-19 caused by SARS-CoV-2 [2596844].

In January 2021, Novavax entered into an Advance Purchase Agreement with the Commonwealth of Australia for the purchase of 51 million doses of NVX-CoV2373 with a target of delivering initial doses by mid-2021. As part of the agreement, Australia had the option to purchase up to an additional 10 million doses. At that time, the company planned to work with Australia's regulatory agency, the Therapeutics Goods Administration (TGA), to obtain product approvals upon demonstrating efficacy in clinical studies [2389282]. In May 2021, a rolling review process was initiated with Australian Therapeutic Goods Administration [2451131]. In August 2021, the filing was expected to complete within weeks of a completed UK MHRA filing, which was expected in 3Q21 [2506188]. In October 2021, completion of the regulatory filing in Australia was expected ‘shortly’ [2556077]. Later that month, the rolling submission for provisional approval of the vaccine was completed in Australia [2557336]. In January 2022, the TGA granted approval for provisional registration of the vaccine, as Nuvaxovid, for active immunization in individuals 18 years of age and older for the prevention of COVID-19 caused by SARS-CoV-2 [2600957].

In December 2020, Novavax entered into an Advance Purchase Agreement with the government of New Zealand for the purchase of 10.7 million doses of NVX-CoV2373. Under the terms of the agreement, Novavax would manufacture NVX-CoV2373 with a target of delivering initial doses by mid-2021. At that time, the company planned to work with Medsafe, New Zealand's regulatory agency, to obtain product approvals as needed [2380500]. In May 2021, a rolling review process was initiated with New Zealand Medsafe [2451131]. In August 2021, the filing was expected to complete within weeks of a completed UK MHRA filing, which was expected in 3Q21 [2506188]. In October 2021, completion of the regulatory filing in New Zealand was expected ‘shortly’ [2556077]. In November 2021, the filing for provisional approval was completed [2559849].

PREMARKETING

PHASE III

In May 2021, a University of Birmingham -sponsored, open-label, randomized, phase III trial (ISRCTN15354495 ; OCTAVE DUO; RG_21-112; IRAS 302634) was initiated in the UK to determine across a range of immune-mediated/immunosuppressive diseases whether re-vaccination with tozinameran , elasomeran or NVX-CoV2373 increased the magnitude of SARS-CoV-2 immune responses in immunocompromised patients (expected n = 1200) with no or low antibodies after two prior vaccine doses. At that time, the trial was expected to complete in April 2023 [2500326]. In August 2021, data were expected later that year [2517575].

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In January 2021, Serum Institute of India filed an application to the drug controller's office for small domestic bridging trials [2399854]. Later that month, it was reported at the virtual 39th JPMorgan Annual Healthcare Conference that a phase II/III Indian study to be conducted by Serum Institute (enrolling 1600 subjects) was planned to begin enrollment in 1Q21 [2397024]. In February 2021, an observer-blind, randomized, controlled study (ICMR/SII-COVOVAX; CTRI/2021/02/031554) to determine the safety and immunogenicity was planned to begin in healthy volunteers. At that time, the trial was expected to complete in February 2022 [2415674]. In May 2021, enrollment was completed [2451131].

In July 2020, a pivotal phase III trial to evaluate the safety and efficacy of NVX-CoV2373 was planned to begin in autumn 2020 [2303727]. In September 2020, it was presented at the virtual World Vaccine Congress that a phase III study in the US was expected to begin in mid-October 2020. The study was expected to enroll 30,000 adults aged >= 18 years, who will receive 5 microg of protein antigen with 50 microg Matrix-M adjuvant versus placebo [2337512]. In November 2020, a randomized, observer-blinded, placebo-controlled phase III study (NCT04611802 ; 2019nCoV-301; PREVENT-19) was planned to begin later that month in US, Puerto Rico and Mexico to assess the effectiveness, immune response and safety of NVX-CoV2373 in adults 18 years of age and older (n = 29,960). The primary endpoint was to assess participants with symptomatic mild, moderate, or severe COVID-19. At that time, the study was expected to complete in December 2022 [2354713]. Later that month, the pivotal trial was planned to begin in the US and Mexico by the end of November 2020 [2358543]. In December 2020, the PREVENT-19 trial began in the US and Mexico [2384712]. Later that month, enrollment was initiated [2385246]. At that time, the trial was initiated in Puerto Rico [2354713]. Further, the trial was ongoing in the US site and expected to recruit up to 500 participants at the University of Maryland School of Medicine [2389442]. In January 2021, it was reported at the virtual 39th JPMorgan Annual Healthcare Conference that as of January 10, 2021, 5709 participants had been enrolled with the demographic enrollment goals met [2397024]. Later that month, the trial randomized over 16,000 participants and also expected to complete the enrollment of 30,000 patients in the first half of February [2398778]. In February 2021, enrolment of all the 30,000 patients was completed in the US and Mexico [2409992]. In April 2021, a crossover arm was planned, and initial clinical data were expected in 2Q21. The company planned to expand the trial to include pediatric and adolescent arms in 2Q21 [2431134]. In May 2021, crossovers were initiated. Also, the company began a pediatric expansion of the trial in up to 3,000 adolescents aged 12 to 17 across up to 75 sites in the US. The subjects would receive either the vaccine or placebo in two dose, administered 21 days separately and a blinded crossover was planned to take place 6 months, after the initial set of vaccinations and the subjects would be monitored for safety up to two years following the final dose. At that time, an update regarding the arm would be presented at the virtual 21st Annual World Vaccine Congress [2446097], [2451131]. In June 2021, positive topline data were reported. The trial met its primary endpoint, with NVX-CoV2373 demonstrating 90.4% efficacy in preventing symptomatic COVID-19 disease (14 cases in the vaccine group versus 63 in the placebo group), including 100% efficacy against moderate or severe disease (10 moderate cases and 4 severe cases in the placebo group). The vaccine also met its secondary endpoint, demonstrating 100% efficacy against variants not considered of concern or of interest (10 sequenced cases in the placebo group). Key exploratory secondary endpoints were also met, including 93.2% efficacy in variants of concern or of interest (6 cases in the vaccine group versus 38 in the placebo group). The vaccine also showed 91% efficacy among high-risk population (> 65 years of age, < 65 years of age with certain comorbidities, or having life circumstances with frequent COVID-19 exposure; 13 cases in the vaccine group versus 62 in the placebo group) [2475668], [2476398]. By August 2021, enrollment in the pediatric expansion part was completed with 2248 adolescents aged 12 to 17 years [2506188]. By November 2021, crossover arms in the trial were completed [2560964]. In December 2021, an extension of the PREVENT-19 trial was initiated to assess booster (third) doses of the vaccine in subjects from the PREVENT-19 trial who received either placebo, with or without subsequent vaccination with other COVID-19 vaccines, or NVX-CoV2373. The primary endpoint was PCR-confirmed COVID-19 at least 7 days after the booster dose [2588012]. In December 2021, data from the pediatric expansion of the PREVENT-19 trial were reported, showing strong immune responses in adolescents that were 2- to 4-fold higher than in adults [2588517]. In December 2021 data from the trial were published [2584736], [2421531].

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In August 2020, a randomized, double-blind, placebo-controlled, efficacy, phase III trial was planned to initiate in COVID-19 patients (expected n = 9,000) in the UK in 3Q20. The study would evaluate the ability of NVX-CoV2373 to protect against symptomatic COVID-19 and antibody and T-cell responses [2309135]. Later in the month, Novavax planned to initiate phase III trials 'as early as October' [2310573]. In September 2020, the trial was initiated (expected n = 10,000). The trial was designed to enroll at least 25 % of participants over the age of 65 as well as to prioritize groups that are most affected by COVID-19, including racial and ethnic minorities. Additionally, up to 400 participants would also receive a licensed seasonal influenza vaccine as part of a co-administration sub-study . The primary endpoint was first occurrence of PCR-confirmed symptomatic COVID-19 with onset at least seven days after the second study vaccination in volunteers who had not been previously infected with SARS-CoV-2 [2328787]. In October 2020, the trial (NCT04583995 ; 2019nCoV-302; 2020-004123-16) was expected to complete in January 2022 [2341991]. Later that month, efficacy data were expected in March 2021 [2340857]. In November 2020, efficacy data along with interim data were expected in the early first quarter of 2021 [2354308]. In November 2020, enrollment was completed in the trial [2369006]. In January 2021, top-line data along with efficacy data were reported which demonstrated, the first interim analysis of COVID-19 were observed resulting in a vaccine efficacy of 89.3% and based on PCR performed on strains from 56 of the 62 cases, efficacy by strain calculated to be 95.6% against the original COVID-19 strain and 85.6% against the UK variant strain and the primary endpoint was met [2398778]. In March 2021, further data showed that NVX-CoV2373 demonstrated a final efficacy of 96.3% against mild, moderate and severe disease caused by the original COVID-19 strain and 86.3% effective against the B.1.1.7 variant. The overall vaccine efficacy was 89.7% [2421430]. Later that month, further data were reported showing efficacy of 96.4% against the original virus strain. There were 106 COVID-19 cases observed, with 10 in the vaccine group and 96 in the placebo group. NVX-CoV2373 was effective against severe disease: five severe cases were observed in the study, and all occurred in the placebo group. Four of the five severe cases were attributed to the B.1.1.7/501Y.V1 variant. Fourteen days after dose 1, vaccine efficacy was 83.4% [2420673]. In April 2021, crossover arms were initiated [2431134]. In May 2021, enrollment was ongoing in the trial [2460432]. In May 2021, a preprint of the full results from the study conducted in adults (n = 15,187) were published [2460431], [2474143]. In June 2021, similar data were published [2487855], [2485785]. In July 2021, data were presented from a sub study in which patients were treated with NVX-CoV2372 along with influenza vaccine at the 31st ECCMID. The sub-study enrolled 217 and 214 subjects to carry on receiving NVX-CoV2373 or placebo, respectively, with a licensed influenza vaccine in the opposite arm. Local reactogenicity recorded an increase in reported local adverse events (AEs) with the combination (approximately 70% with NVX-CoV2373 plus influenza vaccine compared with 57% without; 40 and 20% for placebo with and without) with the main events with pain and tenderness. Systemic AEs were seen in 60 versus 45% and 50 versus 35%) but were overall quite similar when broken down, with the main difference being fatigue (30 versus 20%, approximately for both groups) and muscle pain (30 versus 20%, 20 versus 15%) [2488796], [2480553]. By August 2021, the crossover arms were completed [2506188]. In November 2021, data from the NVX-CoV2373 plus influenza vaccine were published [2570492], [2580341].

PHASE II

In December 2021, data from a phase II boost trial were reported, showing that a two-dose regimen of the vaccine produced cross-reactive immune responses against the B.1.1.529 (Omicron) variant; a third dose increased the immune response [2588517].

In September 2021, a University of Oxford-led phase II study (Com-COV3) to evaluate the potential for combined regimens that mix vaccines from different manufacturers, including NVX-CoV2373, mRNA-1273 and BNT-162b2, in adolescents (aged 12 to 16; expected n = 360) was being planned [2530243], [2530910], [2530913].

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In June 2021, data on the ability of sera, isolated from 30 randomly selected individuals who had participated in a phase II clinical trial and who had received a second dose of the vaccine, to neutralize Alpha (B.1.1.7) and Beta (B.1.351) strains were reported. Similar and a small reduction in neutralizing capacity was demonstrated for the Alpha (B.1.1.7) and Beta (B.1.351) strains, respectively, compared with NVX-CoV2373 [2475222].

In April 2021, the company planned to participate in an University of Oxford-led, non-inferiority, phase II (Com-COV2) study, to evaluate the potential for combined regimens that mix vaccines from different manufacturers to achieve immune protection against COVID-19, in adult volunteers (expected n = 2886; aged >50 years), who received their first vaccination during the prior 8-12 weeks. Among them 350 volunteers were expected to be administered with NVX-CoV2373 among four COVID-19 vaccines [2436524]. In May 2021, topline data were expected in 3Q21 [2451131]. Later that month, the single-blind, randomized, multicentre, phase II trial to determine reactogenicity and immunogenicity of booster vaccination against COVID-19 was planned to begin in the UK in the first week of June [2460423]. In June 2021, The Coalition for Epidemic Preparedness Innovations (CEPI) provided funding to expand the study to include two additional vaccines (Moderna and Novavax) distributed through COVAX [2464134]. In October 2021, initial data were presented at the World Vaccine Congress in Barcelona, Spain. The vaccine was well tolerated and generated a robust immune response when given as a second dose in an heterologous regimen with either Oxford/AstraZeneca or Pfizer/BioNTech vaccines as the first dose [2551863].

In January 2021, it was reported at the virtual 39th JPMorgan Annual Healthcare Conference that a phase II study in the Czech Republic was planned, with enrollment expected 1Q21 [2397024].

In May 2020, a phase II trial was planned [2276909]. In August 2020, the randomized, observer-blinded, placebo-controlled, investigator-initiated, phase IIb trial (NCT04533399 ; 2019nCoV-501) was initiated in South Africa. The trial included two cohorts, where one cohort would evaluate efficacy, safety and immunogenicity of NVX-CoV2373 in healthy adults (expected n = 2665), while the second cohort would evaluate safety and immunogenicity in medically stable, HIV-positive adults (expected n = 240). The primary endpoints were safety, serum IgG antibody levels and HIV- participants with symptomatic moderate or severe COVID-19. At this time the study was expected to conclude in November 2021 [2309422], [2337512]. In November 2020, enrollment was completed in the trial [2369006]. In December 2020, the trial fully enrolled with 4,422 volunteers [2385246]. In January 2021, it was reported at the virtual 39th JPMorgan Annual Healthcare conference that preliminary data were expected in early 1Q21 [2397024]. Later that month, topline data were reported which demonstrated 60% efficacy for the prevention of COVID-19 observed in 94% of the study population that was HIV-negative [2398778]. In March 2021, further data showed that overall efficacy was 48.6% and all five cases of severe disease observed in the trial occurred in the placebo group. Among HIV-negative participants, 55.4% efficacy was observed. The complete analysis showed that (primary endpoint) vaccine-induced protection began 14 days after dose 1, although increased efficacy was observed 7 days after dose 2 [2420673]. In April 2021, crossover arms were initiated [2431134]. In May 2021, data were published, noting that vaccine efficacy among HIV-negative participants was 60.1%; of 41 sequenced isolates, 38 (92.7%) were the B.1.351 variant [2451131], [2464101]. By November 2021, crossover arms in the trial were completed [2560964].

PHASE I/II

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In January 2021, it was reported at the virtual 39th JPMorgan Annual Healthcare Conference that a phase I/II study in Japan was planned, with enrollment planned for 1Q21 [2397024]. Later that month, an interventional, randomized, observer-blind, placebo-controlled, quadruple-blinded, phase I/II trial (NCT04712110 ; TAK-019-1501; U1111-1262-6244) was expected to begin in February 2021 in Japan in healthy Japanese male and female adults (expected n = 200) aged 20 years and older. At that time, the trial was expected to complete in April 2022 [2412154]. In February 2021, the first subject was dosed in the trial. At that time, results were expected in 2H21 [2411374]. In May 2021, enrollment of 200 participants were completed [2451131]. By December 2021, interim data had showed that two doses of the vaccine produced robust anti-SARS-CoV-2 immune responses [2586721].

In February 2020, a phase I clinical trial was planned in June 2020 [2249020]. In March 2020, the trial was planned to initiate in late spring of 2020 or 'within the next four months' [2253713], [2253717]. Later in the month, the initiation of the phase I trial was expected in May or June 2020 [2254167]. In April 2020, two-part, randomized, observer-blinded, placebo-controlled, parallel assignment, phase I/II trial (NCT04368988 , 2019nCoV-101) was planned to initiate in May 2020 in Australia to assess the immunogenicity and safety of SARS-CoV-2 rS nanoparticle vaccine with or without Matrix-M adjuvant in healthy subjects (expected n = 131) to 59 (inclusive) years of age. At that time, the trial was expected to complete in July 2021 [2274150]. Later that month, preliminary results from the trial were expected in July 2020 [2263947]. In May 2020, the first participants was recruited and phase II portion of trial was planned after getting successful phase I results [2281943]. Later that month, the phase II trial was expected to be conducted in the US [2282793]. In June 2020, patient dosing was begun in the study [2287239]. In July 2020, data from the phase I part including preliminary immunogenicity and safety were expected during the first week of August 2020 and the phase II part of the study was expected to begin shortly thereafter [2303727]. In August 2020, positive data from the trial was reported. Data demonstrated that NVX-CoV2373 induced neutralization with anti-spike IgG antibodies produced in all subjects, after a single dose of vaccine and after Dose 2, 100% of participants developed wild-type virus neutralizing antibody responses. Also found NVX-CoV2373 induced antigen-specific polyfunctional CD4+ T cell responses with a strong bias toward the Th1 phenotype. Over all the vaccine was safe and well tolerated [2306644]. In August 2020, the phase II portion of the trial was planned to begin in the US and Australia in the near future in subjects (expected n = 1,500) including older adults [2309422]. Later that month, the phase II portion of the trial was initiated and enrolled first volunteers (expected n = 1500) including older adults 60-84 years of age as approximately 50 percent of the trial's population in the US and Australia. The primary objective was the expand evaluation of immunogenicity and safety. At that time, the interim data were expected in the fourth quarter of 2020 [2311246]. In September 2020, further data were reported. Data demonstrated that the drug was well-tolerated with mild reactogenicity events and no severe adverse events and a favorable product profile [2314553]. Later that month, positive further clinical data were reported. Data demonstrated that NVX-CoV2373 showed immunogenicity safely and elicited immune responses were exceeded than in Covid-19 convalescent serum on day 35 [2315257], [2317462]. In December 2020, data from continuation trial were expected as early as first quarter 2021 [2385246]. In January 2021, similar data from the phase I study were presented at the virtual 39th JPMorgan Annual Healthcare Conference. A continued robust immune response through 6 months was seen. The Matrix-M adjuvant was required for optimal immune response and 2 adjuvanted doses were superior to one dose. Phase II data showed data consistent with phase I data with a strong immune response in all age groups and no observable difference between the two doses. NVX-CoV2373 was well tolerated with few reactions; any reaction was mild to moderate in severity with a mean duration of approximately two days. There was more local reactogenicity after the second dose and lower amount of reactogenicity in older adults. Grade 4 events were observed in the placebo group only. The phase I/II data informed the dosage selection of 5 microg for late-stage development [2397024]. In February 2021, the trial was ongoing [2401922]. In May 2021, 6-month booster doses were completed in the US and Australia. At that time, immunology results were expected to be reported in 3Q21 [2451131]. In August 2021, preliminary data were reported demonstrating that a single booster dose of NVX-CoV2373 given 6 months after an initial two-dose regimen, elicited a 4.6-fold increase in functional antibody titers. Additionally, functional ACE-2 binding inhibition antibodies cross-reactive with the Delta (B.1.617.2) variant were more than 6-fold higher than the primary vaccination series [2506183]. By November 2021, a 12-month booster dose for select patients who completed the 6-month booster part had been initiated [2560964].

PRECLINICAL

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In December 2021, the company was evaluating the vaccine against the Omicron variant. Novavax was to test whether antibodies from previously vaccinated individuals could neutralize the Omicron variant and lab-based data were expected in the coming weeks [2576850].

In June 2021, preclinical data were reported from mice immunized with NVX-CoV2373 or rS-B.1.351 alone, in combination, or as a heterologous prime boost. Mice vaccinated with any of the four regimens had elevated antibody titers against both the original and Beta (B.1.351) spike. Heterologous or bivalent vaccination was highly immunogenic against the prototype spike compared with monovalent vaccination, and immunization with monovalent rS-B.1.351 or bivalent spike resulted in the highest anti-B.1.351 spike IgG titers among the evaluated regimens. Immunization of mice with rS-B.1.351 alone led to elevated neutralizing antibody titers against the Alpha (B.1.1.7) and Beta (B.1.351) strains compared with titers following immunization with the prototype-directed strain. Similar titers were observed in the heterologous and bivalent vaccine cohorts. The antibodies generated following vaccination with rS-B.1.351 had similar effects on inhibiting binding between human angiotensin converting enzyme-2 receptor (hACE2) and the variant spike or the original spike. NVX-CoV2373 was less efficient at eliciting protection against the Beta (B.1.351) variant strain. Regardless of the regimen (immunized with prototype vaccine or rS-B.1.351 alone, in combination, or as a heterologous prime boost), mice were protected following a challenge with live Alpha (B.1.1.7) or Beta (B.1.351) variant strains of SARS-CoV-2 [2475222].

In May 2021, preclinical data were reported. Data showed that compared to hamsters that received the NVX-CoV2373 vaccine alone, hamsters that received the combination NanoFlu/NVX-CoV2373 vaccine reported elevated levels of SARS-CoV-2 anti-S IgG 2 weeks after the first immunization, which increased significantly after a second dose. Compared to non-infected animals and those immunized with NVX-CoV2373 alone, animals immunized with NanoFlu/NVX-CoV2373 retained their body weight [2451066].

In May 2021, preclinical data were reported. Data demonstrated that B.1.351 variant strain vaccine candidate showed strong antibody response and functional immune response in non-human primates [2451131]. In June 2021, further data were reported. In baboons immunized with prototype vaccine and boosted at approximately one year with one or two doses of rS-B.1.351, seven days after the first rS-B.1.351 boost, baboons that had received adjuvanted prototype-directed vaccine demonstrated a strong immune response, with anti-Spike IgG titers higher than the peak immune response observed during the primary immunization series. Additionally, the rS-B.1.351 boost elicited comparable antibody titers against original and rS-B.1.351 spike protein. A strong neutralizing response to Alpha (B.1.1.7) and Beta (B.1.351) strains and a hACE2-inhibiting antibody response following the boost were also observed; prior to the boost, the titers were undetectable [2475222].

In February 2021, preclinical data were reported which demonstrated NVX-CoV2373 induced antibodies that block binding of spike protein to cellular receptors and provided protection from infectious diseases and also vaccine was well-tolerated and elicited robust antibody response [2406942].

By August 2020, data from non-human primate models were presented indicating that the vaccine showed protection in challenge studies, enhanced multifunctional T cells, and produced anti-S IgG and neutralizing antibodies [2307989]. In January 2021, similar data were presented at the virtual 39th JPMorgan Annual Healthcare Conference. In rhesus macaques,NVX-CoV2373 protected the lower and upper airways with no viral replication observed following the day 38 challenge, suggesting prevention of disease and disruption of transmission [2397024].

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In April 2020, preclinical data were reported. Data showed to be highly immunogenic in animal models measuring spike protein-specific antibodies, antibodies that block the binding of the spike protein to the receptor and wild-type virus neutralizing antibodies. High levels of spike protein-specific antibodies with ACE-2 human receptor binding domain blocking activity and SARS-CoV-2 wild-type virus neutralizing antibodies were observed after a single immunization. In addition, the already high microneutralization titers seen after one dose increased eight fold with a second dose. High titer microneutralizing antibodies were generally accepted evidence that a vaccine is likely to be protective in humans [2263947].

In February 2020, protein has been expressed stably in company's baculovirus system. At that time, studies in multiple nanoparticle vaccine candidates in animal models to identify an optimal candidate was ongoing [2249020].

ADDITIONAL INFORMATION

In June 2021, Novavax expected to reach a manufacturing capacity of 100 million doses per month by the end of 3Q21 and 150 million doses per month by the end of 4Q21 [2475668]. By the end of 3Q21, capacity of 100 million doses per month was achieved; in November 2021, the company was on track to achieve capacity of 150 million doses per month by the end of 4Q21 and expected to have capacity of > 2 billion annual doses in 2022 [2560964].

In March 2021, GSK and UK Government Vaccines Taskforce agreed in principle to support manufacturing of up to 60 million doses of the vaccine for use in the UK [2428026].

In February 2021, Takeda would receive a manufacturing technology transfer from Novavax and would be responsible for the development and commercialization based on manufacturing capacity of over 250 million doses of TAK-019 [2411374]. In May 2021, the MHLW was in contract discussions with Takeda for the vaccine with the premise that it would issue an order of 150 million doses [2450474].

In July 2020, mass production was scheduled to start in early 2021 [2304369]. In September 2020, the global supply chain was expected to deliver over two billion doses of NVX-CoV2373 annually in 2021 and the planned capacity was expected to be brought online by mid-2021 [2321412].F

In January 2021, Baxter signed an agreement with Novavax to manufacture and distribute the vaccine in the UK and European markets. The vaccine would be stable at 2°C to 8°C and manufactured in a ready-to-use liquid formulation [2390725].

DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country/ Territory	Development Status	Date
Novavax Inc	Coronavirus disease 19 infection	Australia	Registered	19-Jan-2022
Serum Institute of India Ltd	Coronavirus disease 19 infection	Philippines	Registered	17-Nov-2021
Novavax Inc	Coronavirus disease 19 infection	Philippines	Registered	17-Nov-2021
Serum Institute of India Ltd	Coronavirus disease 19 infection	India	Registered	28-Dec-2021

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Company	Indication	Country/ Territory	Development Status	Date
Novavax Inc	Coronavirus disease 19 infection	Indonesia	Registered	01-Nov-2021
SK Bioscience	Coronavirus disease 19 infection	South Korea	Registered	12-Jan-2022
Novavax Inc	Coronavirus disease 19 infection	EU	Registered	20-Dec-2021
Serum Institute of India Ltd	Coronavirus disease 19 infection	Indonesia	Registered	01-Nov-2021
Novavax Inc	Coronavirus disease 19 infection	UK	Pre-registration	16-Jan-2021
Novavax Inc	Coronavirus disease 19 infection	New Zealand	Pre-registration	10-May-2021
Novavax Inc	Coronavirus disease 19 infection	Canada	Pre-registration	04-Feb-2021
Takeda Pharmaceutical Co Ltd	Coronavirus disease 19 infection	Japan	Pre-registration	15-Dec-2021
Novavax Inc	Coronavirus disease 19 infection	South Africa	Pre-registration	10-Jan-2022
Novavax Inc	Coronavirus disease 19 infection	US	Pre-registration	04-Feb-2021
Novavax Inc	Coronavirus disease 19 infection	Singapore	Pre-registration	24-Nov-2021
Novavax Inc	Coronavirus disease 19 infection	United Arab Emirates	Pre-registration	13-Dec-2021
Novavax Inc	Coronavirus disease 19 infection	Puerto Rico	Phase 3 Clinical	27-Dec-2020
Novavax Inc	Coronavirus disease 19 infection	Mexico	Phase 3 Clinical	28-Dec-2020
Novavax Inc	Coronavirus disease 19 infection	South Korea	Outlicensed	15-Feb-2021
Novavax Inc	Coronavirus disease 19 infection	Japan	Outlicensed	07-Aug-2020
Novavax Inc	Coronavirus disease 19 infection	India	Outlicensed	06-Aug-2020

HISTORICAL DEVELOPMENT STATUS

Company	Indication	Country/ Territory	Development Status	Date
Novavax Inc	Coronavirus disease 19 infection	US	Discovery	21-Jan-2020
Novavax Inc	Coronavirus disease 19 infection	Australia	Preclinical	16-Apr-2020
Novavax Inc	Coronavirus disease 19 infection	US	Preclinical	26-Feb-2020
Novavax Inc	Coronavirus disease 19 infection	UK	Preclinical	14-Aug-2020
Novavax Inc	Coronavirus disease 19 infection	US	Phase 2 Clinical	24-Aug-2020

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Company	Indication	Country/ Territory	Development Status	Date
Novavax Inc	Coronavirus disease 19 infection	Mexico	Preclinical	02-Nov-2020
Novavax Inc	Coronavirus disease 19 infection	Puerto Rico	Preclinical	02-Nov-2020
Novavax Inc	Coronavirus disease 19 infection	UK	Phase 3 Clinical	24-Sep-2020
Serum Institute of India Ltd	Coronavirus disease 19 infection	India	Discovery	06-Aug-2020
Novavax Inc	Coronavirus disease 19 infection	US	Phase 3 Clinical	28-Dec-2020
Takeda Pharmaceutical Co Ltd	Coronavirus disease 19 infection	Japan	Discovery	07-Aug-2020
Takeda Pharmaceutical Co Ltd	Coronavirus disease 19 infection	Japan	Preclinical	15-Jan-2021
SK Bioscience	Coronavirus disease 19 infection	South Korea	Discovery	15-Feb-2021
Novavax Inc	Coronavirus disease 19 infection	New Zealand	Discovery	16-Dec-2020
Novavax Inc	Coronavirus disease 19 infection	Australia	Phase 2 Clinical	25-May-2020
Serum Institute of India Ltd	Coronavirus disease 19 infection	India	Preclinical	29-Jan-2021
Novavax Inc	Coronavirus disease 19 infection	Indonesia	Pre-registration	05-Aug-2021
Serum Institute of India Ltd	Coronavirus disease 19 infection	Indonesia	Pre-registration	05-Aug-2021
Novavax Inc	Coronavirus disease 19 infection	Philippines	Pre-registration	05-Aug-2021
Serum Institute of India Ltd	Coronavirus disease 19 infection	Philippines	Pre-registration	05-Aug-2021
Takeda Pharmaceutical Co Ltd	Coronavirus disease 19 infection	Japan	Phase 2 Clinical	24-Feb-2021
Novavax Inc	Coronavirus disease 19 infection	EU	Pre-registration	04-Feb-2021
Serum Institute of India Ltd	Coronavirus disease 19 infection	India	Pre-registration	05-Aug-2021
Novavax Inc	Coronavirus disease 19 infection	South Africa	Phase 2 Clinical	17-Aug-2020
SK Bioscience	Coronavirus disease 19 infection	South Korea	Pre-registration	29-Apr-2021
Novavax Inc	Coronavirus disease 19 infection	South Korea	Discovery	13-Aug-2020
Novavax Inc	Coronavirus disease 19 infection	Australia	Pre-registration	10-May-2021

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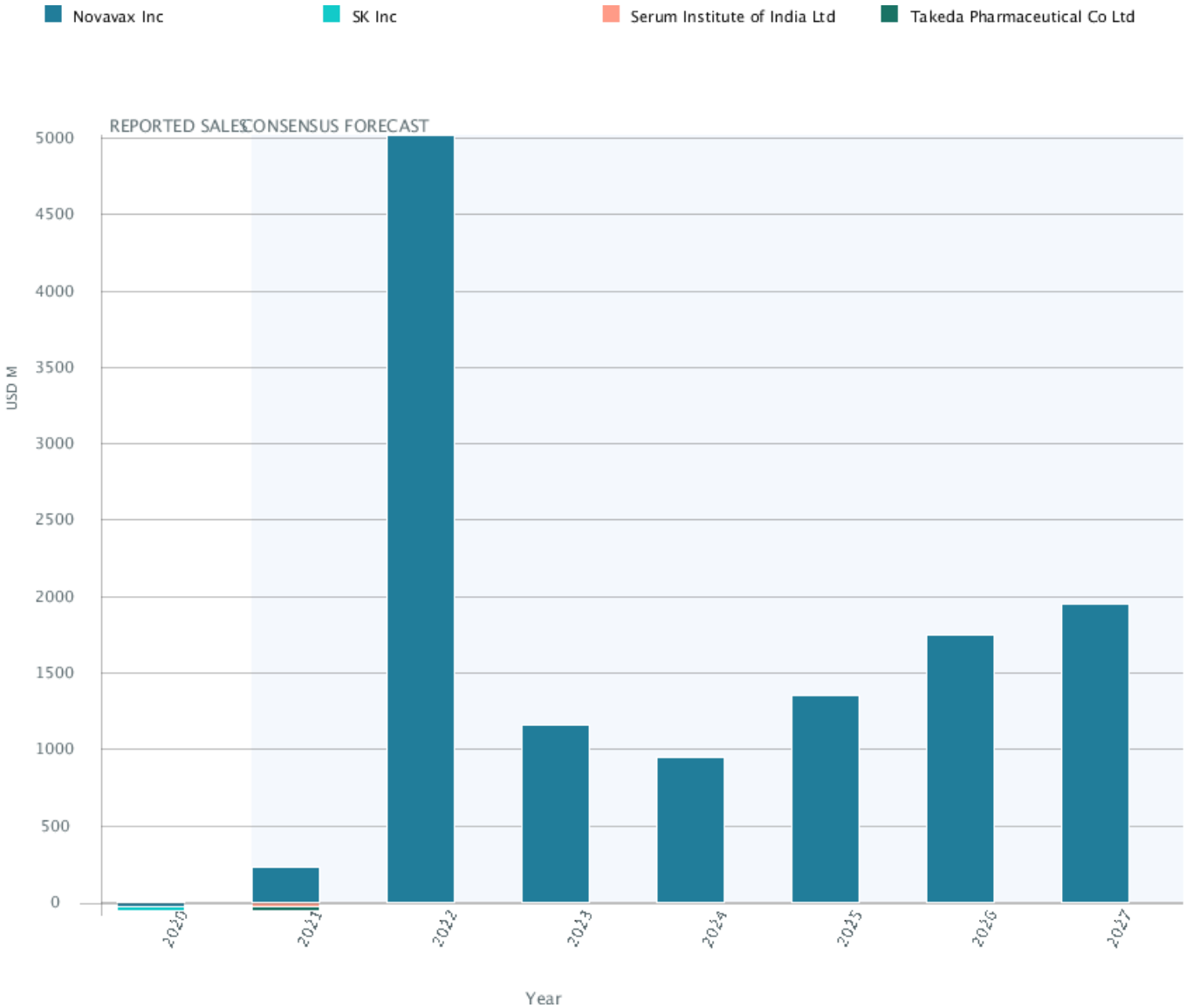
SALES AND FORECASTS

Total Sales By Company



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BROKER RESEARCH BY COMPANY

Year	Company	Franchise	Broker	Date	Value	Consensus
2021	Novavax Inc	COVID-19	Undisclosed 1	21-Jan-2022	0.00	232.50
	Serum Institute of India Ltd	COVID-19	Undisclosed 2	20-Apr-2021	0.00	0.00
	Takeda Pharmaceutical Co Ltd	COVID-19	Company Publication	11-May-2021	0.00	0.00
	Total					232.50
2022	Novavax Inc	COVID-19	Undisclosed 1	21-Jan-2022	5035.00	5017.50
	Total					5017.50
2023	Novavax Inc	COVID-19	Undisclosed 1	21-Jan-2022	1160.00	1160.00
	Total					1160.00
2024	Novavax Inc	COVID-19	Undisclosed 1	21-Jan-2022	950.00	950.00
	Total					950.00
2025	Novavax Inc	COVID-19	Undisclosed 1	21-Jan-2022	1350.00	1350.00
	Total					1350.00
2026	Novavax Inc	COVID-19	Undisclosed 1	21-Jan-2022	1750.00	1750.00
	Total					1750.00
2027	Novavax Inc	COVID-19	Undisclosed 1	21-Jan-2022	1950.00	1950.00
	Total					1950.00

* Due to the use of embargoed data, the number of analysts that comprise the Consensus value may differ from the number of listed Broker Reports.

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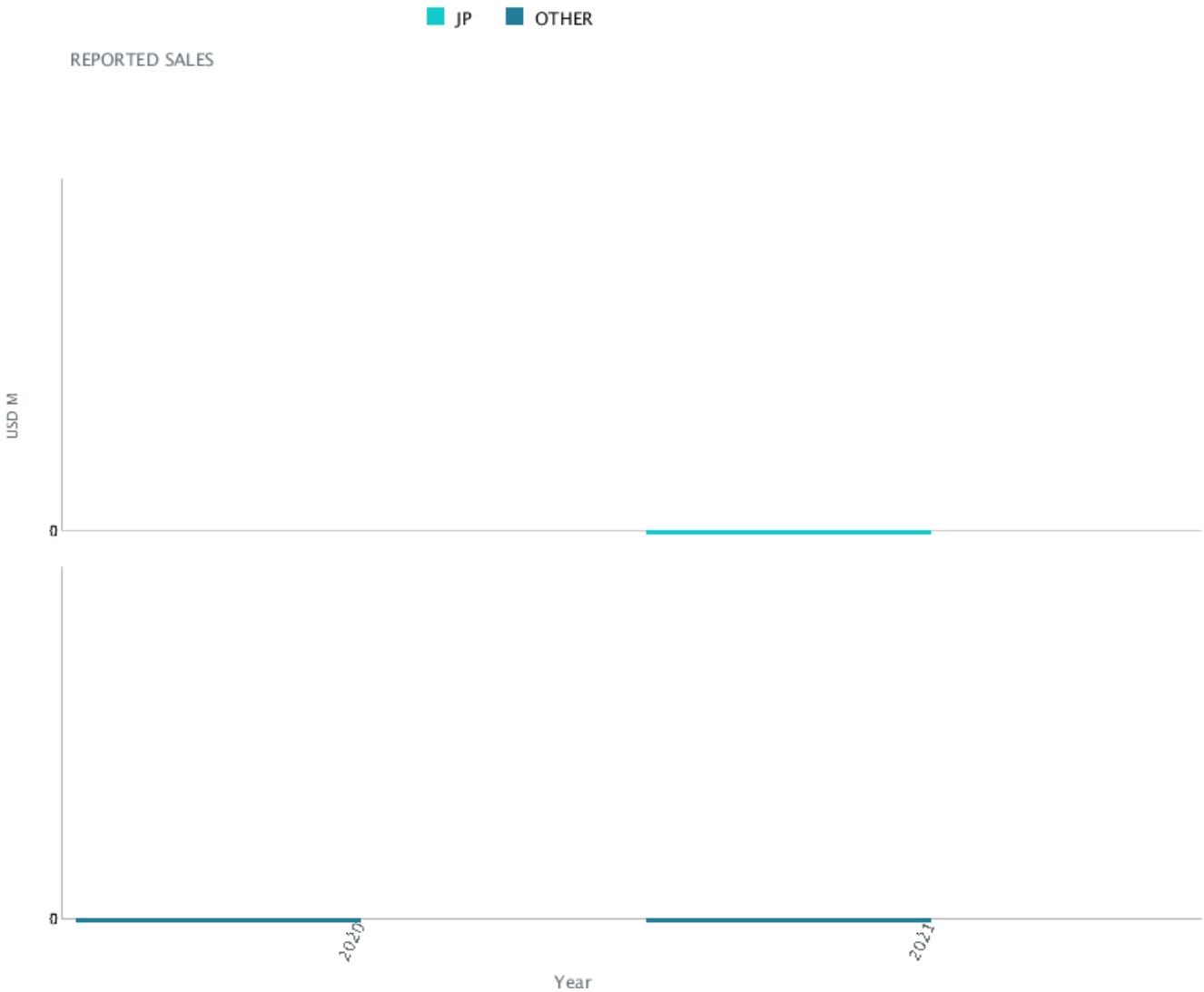
Total Sales By Region



BROKER RESEARCH BY REGION

Year	Company	Region	Franchise	Broker	Date	Value
2021	Serum Institute of India Ltd	OTHER	COVID-19	Undisclosed 1	20-Apr-2021	0.00
	Takeda Pharmaceutical Co Ltd	JP	COVID-19	Company Publication	11-May-2021	0.00

* Due to the use of embargoed data, the number of analysts that comprise the Consensus value may differ from the number of listed Broker Reports.

COMMENTARY

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CONSENSUS SALES INFORMATION

Consensus forecast data, where available, are presented for Novavax , Takeda Pharmaceutical , Serum Institute of India and SK Group (the parent company of SK Bioscience).

REGIONAL DEVELOPMENT AND MARKETING RIGHTS

In August 2020, SK Bioscience entered into a development and supply agreement to manufacture and supply for Novavax the antigen component of NVX-CoV2373 against COVID-19 worldwide and and in the Korea [2309654], [2310573], [2321412]. In February 2021, the deal was expanded to give SK the right to manufacture and commercialize NVX-CoV2373 in Korea [2406942].

In August 2020, Takeda Pharmaceutical entered into an agreement to develop, manufacture and commercialize NVX-CoV2373 in Japan [2307567]. In February 2021, the parties have finalized the license agreement [2413329].

In July 2020, Serum Institute of India entered into an exclusive agreement to develop and commercialize NVX-CoV2373 for COVID-19 in India and gained non-exclusive rights to commercialize NVX-CoV2373 in other low- and middle-income (LMIC) countries [2307374], [2307405].

CLINICAL TRIALS

Trials by Phase and Condition Studied

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Coronavirus disease 19 infection											
0	0	1	2	6	10	0	0	1	3	8	15
Influenza virus infection											
0	0	0	0	1	1	0	0	0	0	1	1

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Total Trials by Phase and Status

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Total by Phase and Status											
0	0	1	2	6	10	0	0	1	3	8	15

Phase Definitions

Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

SWOT ANALYSIS

COVID-19

Strengths

- NVX-CoV2373 is a subunit vaccine constructed from a baculovirus that contains a gene encoding full-length spike protein stabilized in the prefusion conformation; it is administered with the saponin-based adjuvant Matrix M1 [2500463]
- Overall vaccine efficacy was 89.7% according to a phase III trial conducted in the UK; overall vaccine efficacy in patients older than 65 years was 88.9% [2420673]
- Vaccine efficacy against the original virus strain was 96.4% and against the UK variant (alpha; B.1.1.7) was 86.3% in the same trial [2420673]
- There were no cases of severe COVID among 10 cases of COVID seen in vaccinated patients in the same trial [2420673]

Weaknesses

- Local adverse events were common after both the first (57.6%) and second dose (79.6%) [2487855]
- The most commonly reported adverse events are headache, muscle pain and fatigue; two patients in the phase III trial reported Grade 4 fever (>40 degC) [2487855]
- There was on related serious adverse event in the trial (myocarditis) [2487855]
- Lower efficacy (51%) was shown against the South Africa variant (beta; B.1.351) according to a phase II trial [2475222]
- Efficacy in COVID cases in vaccinated subjects in the PREVENT-19 study caused by variants which were unknown was 75% [2475668]

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- Overall efficacy was 90.4% in the US PREVENT-19 study, with complete prevention of hospitalization and death [2475668]
- Baboons originally immunized with the vaccine who were boosted with a novel prototype vaccine (rS-B.1.351) against the beta B.1.351 variant 1 year later exhibited a strong neutralizing response to both the alpha and beta strains and hACE2-inibiting antibody response following the boost [2475222]
- The vaccine is stable in refrigerated storage and manufactured in a ready-to-use liquid formulation [2390725]
- Fast track designation [2358543]
- Patent exclusivity to 2040 [US-10953089]

Opportunities

- Leverage being the first protein-based COVID-19 vaccine granted Emergency Use Listing by the World Health Organization [2585991]
- The COVID-19 pandemic is the defining global health crisis of our time, and the biggest threat to public health in over a century [2273072]
- The potent efficacy puts the vaccine on par with leading vaccine candidates from Pfizer and Moderna, making it a strong contender among the second wave of vaccines to enter the market [2420673]
- The stability at refrigerator temperatures will allow for wider distribution [2390725]
- Advanced purchase agreements are in place with GAVI to deliver 1.1 billion doses, and there are supply agreements in place with the US, UK, Canada and Australia, as well as provision of 350 million doses for low income countries [2449093], [2428026], [2413428]

Threats

- Late approval and the market in countries with high vaccination rates such as the US and UK would be saturated, and the vaccine would be restricted to booster use which would be more niche [2451131]
- Strong presence of mRNA vaccines, which have been validated and are now widely available, notably Pfizer’s BNT-162b3 and Moderna’s MRNA-1273; Moderna’s vaccine also remains stable at refrigerated conditions [2326866], [2361565]
- AstraZeneca/University of Oxford's AZD-1222, a replication-deficient simian adenovirus vector encoding Spike protein antigen from SARS-CoV-2, which was first launched in the UK in January 2021; the vaccine can be stored at normal refrigerated conditions for at least 6 months and can be distributed and administered within existing healthcare settings [2366140], [2354204], [2387383]

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- Vaccines against COVID are still urgently needed as only 5% of the global population has been fully vaccinated [2499301]
- The early-stage data suggest that in addition to being a primary vaccine candidate, NVX-CoV2373 could be used with a booster vaccine with rS-B.1.351 (either bivalent or as a prime boost for patients already fully vaccinated with NVX-CoV2373), which given the uncertainty on the durability of natural infection or vaccination may be an important way to maintain protection in subsequent epidemic waves [2475222]
- Johnson & Johnson's Ad26 SARS-CoV-2, which received Emergency Use Authorization in February 2021 as a single-shot vaccine; it is compatible with standard vaccine storage and distribution channels with ease of delivery to remote areas [2413556]
- Other recently approved vaccines, such as Dynavax/Sinovac's CoronaVac and CaSino's Ad5-nCoV, which are approved for emergency use in China and regions in South America, Middle East and/or Asia, and others in late-stage development, with over 50 potential vaccine candidates in development [2395888], [2403218], [2412275], [2402631], [2413146]
- Last updated on February 11, 2022

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paclitaxel (albumin-bound, breast cancer), Hunan Kelun Pharmaceutical

SNAPSHOT

Drug Name	paclitaxel (albumin-bound, breast cancer), Hunan Kelun Pharmaceutical
Other Drug Names	paclitaxel; paclitaxel (albumin-bound, undisclosed indication), Hunan Kelun Pharmaceutical; A-026-1; paclitaxel (albumin-bound, breast cancer), Hunan Kelun Pharmaceutical
Originator Company	Hunan Kelun Pharmaceutical Co Ltd
Active Companies	Hunan Kelun Pharmaceutical Co Ltd
Therapy Area	Cancer
Inactive Companies	
Highest Status	Registered
Regulatory Designations	
Active Indications	Breast tumor
Inactive Indications	
Target-based Actions	
Other Actions	Microtubule stabilizer; Anticancer
Technologies	Nanoparticle formulation injectable; Protein conjugated; Intravenous formulation; Biological therapeutic; Pharmaceutical carrier
Franchises	
EphMRA Codes	
Last Change Date	20-Aug-2020
Added Date	04-Jan-2016

DEVELOPMENT PROFILE

SUMMARY

Hunan Kelun Pharmaceutical developed A-026-1, an albumin-bound nanoparticle formulation of paclitaxel for the iv treatment of breast cancer [1717543], [1724343], [2030470]. In August 2020, the drug was approved in China [2310199].

REGULATORY

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In 2015, the company intended to develop the product as a class 1.6 chemical drug in China [1717543]. In January 2019, the company filed a launch application as a class 4 generic chemical drug in China [2107483]. In August 2020, the drug was approved in China [2310199].

PREMARKETING

In February 2018, a corss-over design, randomized, open-label, clinical trial (CTR20181260; KL026-1-BE-01-CTP) was initiated in China to study the bioequivalence and safety of the drug compared to Abraxane in patients (expected n = 24) with breast cancer; in July 2018, the trial was completed in 26 patients [2287369].

In December 2015, an IND was filed in China [1724343].

DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country/ Territory	Development Status	Date
Hunan Kelun Pharmaceutical Co Ltd	Breast tumor	China	Registered	18-Aug-2020

HISTORICAL DEVELOPMENT STATUS

Company	Indication	Country/ Territory	Development Status	Date
Hunan Kelun Pharmaceutical Co Ltd	Breast tumor	China	Preclinical	29-Dec-2015
Hunan Kelun Pharmaceutical Co Ltd	Breast tumor	China	Clinical	07-Feb-2018
Hunan Kelun Pharmaceutical Co Ltd	Breast tumor	China	Pre-registration	02-Jan-2019

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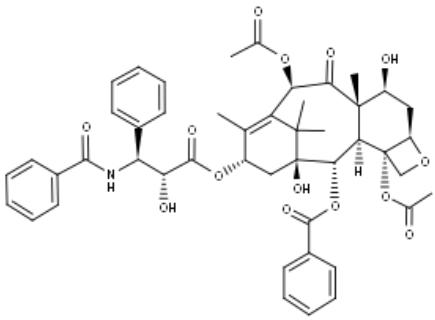
CHEMICAL STRUCTURES

Confidence Level: 1



Name	Type
BMS-181339-01	Research Code
NSC-125973	Research Code
paclitaxel	USAN; BANN; INN
Taxol	Trade Name
Taxol A	
ABI-007	Research Code
NanoTaxel	Trade Name
Taxosomes	Trade Name
Paclical	Trade Name
Abraxane	Trade Name
DHP-107	Research Code
Dermos	Trade Name
DHP-208	Research Code
NMR-2057	Research Code
Genexol-PM	Trade Name
OncoGel	Trade Name
Cobraxane	Trade Name
Nanotax	Trade Name
PoLi-PTX	Research Code

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Name	Type
CT-KT-125	Research Code
NCL-PTX	
PXT-LNC	
PTX-GAGs	
Lipusu	Trade Name
Capxol	Trade Name
KER-1001	Research Code
Taxus	Trade Name
PAXCEED	Trade Name
LBI-0424	Research Code
SOL-606	Research Code
Onxal	Trade Name
Bristaxol	Trade Name
Praxel	Trade Name
Anzatax	Trade Name
NSC-673089	Research Code
Asotax	Trade Name
Pacliex	Trade Name
Apealea	Trade Name
OAS-PAC-100	Research Code
NPG-384	Research Code
Nanoxane	Trade Name
SOR-007	Research Code
nab-paclitaxel	
TSD-001	Research Code

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Name	Type
LM-101	Research Code
LM-102	Research Code
NanoPac	Trade Name
SG-102	Research Code
Abraxus	Trade Name
SB-05PC	Research Code
EndoTAG-1	
LipoPac	Trade Name
MBT-0206	Research Code
SPR-064	Research Code
TENPA	
TBC-1002	Research Code
TYN-21	Research Code
ZSYY-001	Research Code

CLINICAL TRIALS

Trials by Phase and Condition Studied

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Metastatic breast cancer											
0	0	0	0	0	0	0	1	0	0	0	1

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Total Trials by Phase and Status

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Total by Phase and Status											
0	0	0	0	0	0	0	1	0	0	0	1

Phase Definitions

Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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abiraterone acetate (oral nanoparticle formulation/SoluMatrix, prostate cancer), iCeutica/Sun Pharmaceutical

SNAPSHOT

Drug Name	abiraterone acetate (oral nanoparticle formulation/SoluMatrix, prostate cancer), iCeutica/Sun Pharmaceutical
Other Drug Names	abiraterone; abiraterone acetate; IO-1203; prostate cancer therapeutic (SoluMatrix/oral/nanoparticle), iCeutica/Churchill Pharma; IC-1206; ICE-1206; Yonza; abiraterone acetate (oral nanoparticle formulation/SoluMatrix, prostate cancer), iCeutica/Churchill Pharma; YONSA
Originator Company	iCeutica Inc
Active Companies	iCeutica Inc; Sun Pharmaceutical Industries Ltd
Therapy Area	Cancer
Inactive Companies	Churchill Pharmaceuticals LLC
Highest Status	Registered
Regulatory Designations	
Active Indications	Prostate tumor; Hormone refractory prostate cancer
Inactive Indications	
Target-based Actions	Cytochrome P450 17 inhibitor
Other Actions	Anticancer
Technologies	Oral formulation; Nanoparticle formulation oral; Small molecule therapeutic; Tablet formulation
Franchises	
EphMRA Codes	
Last Change Date	08-Jul-2020
Added Date	08-May-2012

DEVELOPMENT PROFILE

SUMMARY

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iCeutica, and its licensee, Sun Pharma are developing ICE-1206 (IC-1206; presumed to be IO-1203; Yonza; YONSA), an oral nanoparticle (ultramicrosized) formulation of abiraterone acetate, a Cytochrome P450 17A1 (CYP17) inhibitor, using its SoluMatrix platform, for the potential treatment of prostate cancer [1287847], [1393994], [1478639], [1754523], [1795931], [1930147], [2036746]. In May 2018, an NDA filing was approved by the US FDA for the treatment of metastatic castration-resistant prostate cancer in combination with methylprednisolone [2036746]. In September 2013, the company was seeking to outlicense the program [1478639].

Churchill Pharma was previously developing ICE-1206, for the potential treatment of prostate cancer [1287847], [1393994], [1478639], [1754523], [1795931], [1930147]. However in May 2018, Sun Pharma acquired development and commercialization rights from Churchill Pharma for YONSA in the US [2036746].

REGULATORY

In May 2017, a NDA was submitted to the US FDA for YONSA for the treatment of metastatic castration-resistant prostate cancer in combination with methylprednisolone [1930147]. In July 2017, the US FDA accepted the filing of the NDA for YONSA. At that time, the FDA expected the review to complete by March 19, 2018, under the PDUFA [1946817]. In May 2018, the NDA filing was approved [2036746].

PREMARKETING

In August 2016, an open-label extension, expanded access phase III study (NCT02887976; GURN-AA-201-OLE; STAAR-E), to assess long-term safety of the drug with methylprednisolone (4mg bid) in patients (expected n = 15) with prostate cancer and completed study number CHL-AA-201, was to begin in the US, in September 2016. At that time, completion of the study was expected in December 2017 [1795931], [1930147]. In February 2018, positive data from the trial were presented at the 2018 ASCO Genitourinary Cancers Symposium in San Francisco, CA. Data demonstrated that the safety profile of YONSA, in patients treated for up to one year, more than 50% of whom had been previously treated with Zytiga was consistent with safety reported in the literature for Zytiga and that patients who had been on a Zytiga regimen could be safely switched to YONSA [2003040].

In October 2016, an open-label, single-arm, multiple center extension, interventional, phase II study (NCT02962284: CHL-AA-202) was planned to assess the safety and efficacy of abiraterone acetate with methylprednisolone in patients (expected n = 25) with metastatic castration-resistant prostate cancer. At that time, the study was expected to complete in June 2018. In November 2016, the study was initiated in the US [1876003]. In February 2018, clinical data from 20 patients from the STAAR-extension study were presented at the 2018 ASCO Genitourinary Cancers Symposium in San Francisco, CA. As of August 16, 2017, the median abiraterone acetate fine particle formulation treatment duration (STAAR + STAAR-extension) was 178 days. Each one patient discontinued treatment due to progressive disease, fatigue and a fall (non-abiraterone acetate fine particle formulation related) resulting in death. Any AE was reported by 13 patients. Any AEs of grade 3/4/5 was reported by two patients, and each one patient reported injury complications and death, decreased lymphocyte count, decreased neutrophil count, decreased WBC count, intraventricular and subarachnoid hemorrhage and petechiae [2007847].

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In February 2016, a randomized, open-label, active-controlled, multicenter, phase II study (NCT02737332; CHL-AA-201; STAAR) of the drug compared to Zytiga, to evaluate serum testosterone levels in patients (expected n = 50) with metastatic castration-resistant prostate cancer was initiated in the US. The study was to complete in September 2016 [1754523], [1930147]. In February 2017, clinical data were presented at the 2017 ASCO Genitourinary Cancers Symposium in Orlando, FL. In health volunteers receiving 100, 200, 400, 125, 500 and 625 mg abiraterone acetate fine particle in both study 1 and 2 (n = 19, 18, 19, 33, 34 and 34, respectively), mean AUC (0 to t) was 68, 170, 303, 103, 416 and 450 h.ng/ml, respectively, mean AUC (0 to infinity) was 74, 183, 320, 112, 438 and 473 h.ng/ml, respectively, mean Cmax was 17, 39, 65, 28, 84 and 101 ng/ml, respectively, and median Tmax was 1.5, 1.75, 2.0, 1.5, 1.5 and 1.5 h, respectively; while in health volunteers receiving 1000 mg originator abiraterone acetate in both study 1 and 2 (n = 19 and 33, respectively), mean AUC (0 to t) was 387 and 416 h.ng/ml, respectively, mean AUC (0 to infinity) was 421 and 453 h.ng/ml, respectively, mean Cmax was 79 and 83 ng/ml, respectively, and median Tmax was 2.0 and 2.0 h, respectively. The treatment-emergent AEs reported were mostly of grade 1; however abiraterone acetate fine particle-related adverse events (AEs), serious AEs, were not reported during the study and no deaths occurred [1904635]. In July 2017, final data from the trial evaluated in 53 male patients were reported. Data showed that over 90% of patients treated with YONSA achieved absolute testosterone levels of <1 ng/dL at each time point. Furthermore, non-detectable testosterone levels (< / = 0.1 ng/dL) were achieved in a higher percentage of patients treated with YONSA versus patients treated with the comparator [1946817]. In February 2018, positive data were planned to be presented at the 2018 ASCO Genitourinary Cancers Symposium in San Francisco, CA. 24-hour pharmacokinetic results comparing YONSA to Zytiga showed no statistical difference between the two agents despite the lower dose of YONSA. Similar data from the trial were published in the journal Urologic Oncology. Data demonstrated that a majority of the patients had Gleason scores >7. [2003040]. Further patient-subgroup analysis data were presented at the same conference. Of 14 patients, the pharmacokinetic samples were evaluated for 5 and 8 patients in abiraterone acetate fine particle formulation and originator abiraterone acetate treatment groups, respectively. All 12 patients completed the 12 weeks of treatment with no clinical disease progression. In abiraterone acetate fine particle formulation and originator abiraterone acetate treatment groups, at 24 h (at steady state) the least squares mean values for pharmacokinetic parameters like AUC (0-24 h) was 626.07 and 870.86 ng.h/ml, respectively (p = 0.508); Cavg (0-24 h) was 26.08 and 36.29 h, respectively (p = 0.508); Cmax was 111.32 and 268.26 ng/ml, respectively (p = 0.192); Cmin was 3.16 and 6.71 ng/ml, respectively (p = 0.078); and median values of Tmax was 2 and 1.5 h, respectively (p = 0.254); and t1/2 was 8.12 and 9.84 h, respectively (p = 0.177). When compared with the overall study results, the patient subgroup demonstrated clinical benefit [2007820].

In June 2017, clinical data from a randomized, cross-over study which evaluated the relative bioavailability and bioequivalence of abiraterone acetate fine particle + methylprednisolone and a reference formulation with prednisone in 72 healthy male subjects were presented at the 53rd ASCO meeting in Chicago, IL. Subjects were randomized in a crossover design to receive methylprednisolone (4 mg, bid) or prednisone (5 mg, bid) for 12 days in period 1. On day 11 of period 1, subjects given methylprednisolone received a single dose of abiraterone acetate fine particle (500 mg, test) and subjects given prednisone received a single dose of originator abiraterone acetate (1000 mg; reference). After a 2-week steroid washout period, subjects received the alternate treatments in period 2. There were no statistical differences with regard to abiraterone AUC (p >= 0.38) and Cmax (p = 0.22) between abiraterone acetate fine particle and originator abiraterone acetate. Geometric mean ratio (GMR) was 95.9, 99.2 and 116.8% for AUC (0 to infinity), AUC(0 to t), and Cmax, respectively. The coefficient of variance for both AUC and Cmax was smaller for abiraterone acetate fine particle compared with originator abiraterone acetate. Both treatments were safe and well tolerated [1940371].

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In February 2017, clinical data from a study in healthy subjects under fed and fasted conditions were presented at the 2017 ASCO Genitourinary Cancers Symposium in Orlando, FL. In a crossover design, healthy male subjects (n = 25) fasted 10 h overnight were randomized to receive single 500 mg dose of abiraterone acetate fine particle under fasted or fed (high-fat FDA breakfast 30 min before abiraterone acetate fine particle administration) conditions; prior to crossover, there was a 7-day washout period prior. A total of 22 subjects completed the study. Under fed conditions, drug exposure of abiraterone acetate fine particle 500 mg was significantly greater ($p < 0.0001$) compared to fasted conditions. Relative po bioavailability measured by the ratio of test-to-reference geometric means of AUC and Cmax of abiraterone, following a single dose of abiraterone acetate fine particle 500 mg indicated that abiraterone exposure increased under fed conditions by approximately 4.5- and 6.5-fold, respectively, versus under fasted conditions [1904627]. In April 2017, data were published. Data reported that abiraterone acetate fine particle 500 mg was demonstrated to be bioequivalent to 1000 mg of Zytiga in healthy volunteers under fasted conditions [1930147], [1930372].

In March 2013, the drug was listed as being in phase I development [1393994].

By March 2013, Churchill had completed a pre-IND meeting with the FDA and planned to initiate the first clinical trial in 2013 [1395182].

PRECLINICAL

In May 2012, preclinical development was ongoing [1287847].

DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country/ Territory	Development Status	Date
iCeutica Inc	Hormone refractory prostate cancer	US	Registered	23-May-2018
Sun Pharmaceutical Industries Ltd	Hormone refractory prostate cancer	US	Registered	23-May-2018
Sun Pharmaceutical Industries Ltd	Prostate tumor	US	Phase 1 Clinical	23-May-2018
iCeutica Inc	Prostate tumor	Australia	Phase 1 Clinical	21-Mar-2013
Churchill Pharmaceuticals LLC	Prostate tumor	US	Outlicensed	23-May-2018
Churchill Pharmaceuticals LLC	Hormone refractory prostate cancer	US	Outlicensed	23-May-2018

HISTORICAL DEVELOPMENT STATUS

Company	Indication	Country/ Territory	Development Status	Date
Churchill Pharmaceuticals LLC	Prostate tumor	US	Discovery	07-May-2012
iCeutica Inc	Prostate tumor	Australia	Discovery	07-May-2012

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abiraterone acetate (oral nanoparticle formulation/SoluMatrix, prostate cancer), iCeutica/Sun Pharmaceutical

Company	Indication	Country/ Territory	Development Status	Date
Churchill Pharmaceuticals LLC	Hormone refractory prostate cancer	US	Phase 2 Clinical	29-Feb-2016
iCeutica Inc	Hormone refractory prostate cancer	US	Phase 2 Clinical	29-Feb-2016
iCeutica Inc	Hormone refractory prostate cancer	US	Pre-registration	23-May-2017
Churchill Pharmaceuticals LLC	Hormone refractory prostate cancer	US	Pre-registration	23-May-2017
Churchill Pharmaceuticals LLC	Prostate tumor	US	Phase 1 Clinical	21-Mar-2013

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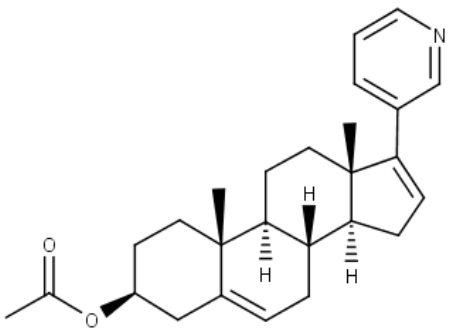
abiraterone acetate (oral nanoparticle formulation/SoluMatrix, prostate cancer), iCeutica/Sun Pharmaceutical

CHEMICAL STRUCTURES

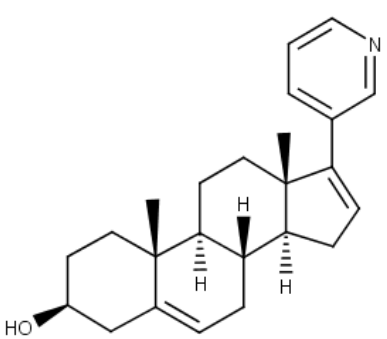
Confidence Level: 1



Name	Type
CB-7630	Research Code
abiraterone acetate	USAN
Zytiga	Trade Name
JNJ-212082	Research Code

CHEMICAL STRUCTURES

Confidence Level: 1



Name	Type
abiraterone	BANN; INN
CB-7598	Research Code
JNJ-589485	Research Code
SOL-804	Research Code
DST-2970	Research Code

CLINICAL TRIALS

Trials by Phase and Condition Studied

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Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Bone tumor											
0	0	0	0	0	0	1	1	0	0	1	1
Metastasis											
0	0	0	0	0	2	0	0	0	0	0	2
Adenocarcinoma											
0	0	0	0	0	1	1	1	0	0	1	2
Prostate tumor											
0	0	0	1	0	0	0	0	0	0	0	1
Hormone refractory prostate cancer											
0	0	0	0	0	2	1	1	0	0	1	3
Soft tissue sarcoma											
0	0	0	0	0	0	1	1	0	0	1	1
Metastatic prostate cancer											
0	0	0	0	0	0	1	1	0	1	1	2

Total Trials by Phase and Status

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Total by Phase and Status											
0	0	0	1	0	2	1	1	0	1	1	5

Phase Definitions

Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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doxorubicin (intravenous nanosomal lipid suspension/Nanoaqualip, cancer), Jina Pharmaceuticals/Intas Pharmaceuticals

SNAPSHOT

Drug Name	doxorubicin (intravenous nanosomal lipid suspension/Nanoaqualip, cancer), Jina Pharmaceuticals/Intas Pharmaceuticals
Other Drug Names	doxorubicin; doxorubicin (intravenous nanosomal lipid suspension/Nanoaqualip, cancer), Jina Pharmaceuticals/Intas Pharmaceuticals; JIN-2019
Originator Company	Jina Pharmaceuticals Inc
Active Companies	Intas Pharmaceuticals Ltd; Jina Pharmaceuticals Inc
Therapy Area	Cancer
Inactive Companies	
Highest Status	Registered
Regulatory Designations	
Active Indications	Cancer
Inactive Indications	
Target-based Actions	Topoisomerase II inhibitor
Other Actions	DNA synthesis inhibitor; Anticancer; DNA intercalator
Technologies	Suspension; Intravenous formulation; Nanoparticle formulation injectable; Lipid; Small molecule therapeutic
Franchises	
EphMRA Codes	
Last Change Date	20-Oct-2019
Added Date	27-Jun-2011

DEVELOPMENT PROFILE

SUMMARY

Jina Pharmaceuticals in collaboration with Intas Pharmaceuticals, has developed a nanosomal lipid suspension of doxorubicin presumed to be JIN-2019, using its Nanoaqualip technology, for the iv treatment of cancer [1203778], [1515630], [1515639]. By January 2014, the drug had been approved in India [1515639].

PRECLINICAL

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In June 2011, JIN-2019 was listed as being in preclinical development [1203778]; this was still the case in January 2013 [1362781].

ADDITIONAL INFORMATION

Jina Pharmaceuticals and Intas Pharmaceuticals developed Nanoaqualip technology, a lipid based nanotechnology in which drugs were formulated in an aqueous medium without the use of toxic solvents during the manufacturing process yielding homogeneous nanoparticle size products [1203778], [1515630].

DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country/ Territory	Development Status	Date
Intas Pharmaceuticals Ltd	Cancer	India	Registered	15-Jan-2014
Jina Pharmaceuticals Inc	Cancer	US	Preclinical	02-Jun-2011

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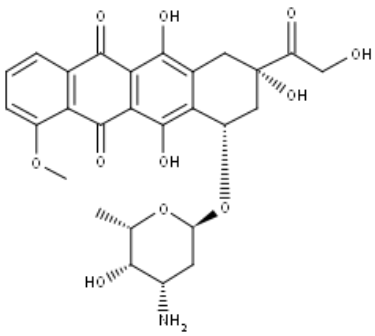
doxorubicin (intravenous nanosomal lipid suspension/Nanoaqualip, cancer), Jina Pharmaceuticals/Intas Pharmaceuticals

CHEMICAL STRUCTURES

Confidence Level: 1



Name	Type
doxorubicin	USAN; BAN; INN
Doxil	Trade Name
MCC-465	Research Code
CD-103	Research Code
LC-100	Research Code
DOX-003	Research Code
SP-1049C	Research Code
JIN-2019	Research Code
Livatag	Trade Name
GL-249	Research Code
Eos-001	Research Code
SA-033	Research Code
BOT-161	Research Code
QR-212	Research Code
Eos-003	Research Code
SPARC-08-038	Research Code
TLD-1	Research Code
Talidox	

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doxorubicin (XR-17 encapsulated, cancer), Oasmia

SNAPSHOT

Drug Name	doxorubicin (XR-17 encapsulated, cancer), Oasmia
Other Drug Names	doxorubicin; doxorubicin (liposomal, cancer), Oasmia; Doxophos; doxorubicin (XR-17 encapsulated, cancer), Oasmia
Originator Company	Oasmia Pharmaceutical AB
Active Companies	Hetero Group; Oasmia Pharmaceutical AB
Therapy Area	Cancer
Inactive Companies	
Highest Status	Registered
Regulatory Designations	
Active Indications	Thyroid tumor; Stomach tumor; Hodgkins disease; Endometrioid carcinoma; Acute lymphoblastic leukemia; Acute myelogenous leukemia; Chronic leukemia; Nephroblastoma; Osteosarcoma; Multiple myeloma; Rhabdomyosarcoma; Neuroblastoma; Prostate tumor; Ewing sarcoma; Non-Hodgkin lymphoma; Soft tissue sarcoma; Germ cell and embryonic cancer; Breast tumor; Head and neck tumor; Cancer; Lung tumor; Ovary tumor
Inactive Indications	
Target-based Actions	DNA polymerase inhibitor; Topoisomerase II inhibitor
Other Actions	Anticancer
Technologies	Nanoparticle formulation; Liposome formulation; Small molecule therapeutic
Franchises	
EphMRA Codes	
Last Change Date	17-Oct-2019
Added Date	03-Jan-2007

DEVELOPMENT PROFILE

SUMMARY

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Oasmia Pharmaceutical has developed Doxophos, a liposomal nanoparticle formulation of the DNA polymerase and topoisomerase II inhibitor doxorubicin and the retinoid encapsulating vehicle XR-17, for the potential treatment of cancer including acute lymphoblastic leukemia, acute myeloblastic leukemia, chronic leukemia, Hodgkin's disease, non-Hodgkin's lymphoma, multiple myeloma, osteogenic sarcoma, Ewing's sarcoma, soft tissue sarcoma, neuroblastoma, rhabdomyosarcoma, Wilms' tumor, breast carcinoma, endometrial cancer, ovarian carcinoma, germ cell tumors, prostatic carcinoma, lung cancer, gastric carcinoma, head and neck cancer and thyroid carcinoma [745872], [754834], [1572353], [1724520], [1951769]. In August 2017, the company received marketing approval of Doxophos in Russia [1951769].

In January 2016, the company submitted a marketing approval application for the Commonwealth of the Independent States [1724520]. However, no further development has since been reported.

Licensee Hetero Group , obtained marketing and distribution rights for the drug in Russia [1951769].

REGULATORY

In January 2016, the company submitted a marketing approval application for Russia and the Commonwealth of the Independent States (CIS). At that time, the market approval was expected by the end of 2016 [1724520]. In August 2017, the company received marketing approval of Doxophos in Russia for the treatment of various types of cancers including, acute lymphoblastic leukemia, acute myeloblastic leukemia, chronic leukemia, Hodgkin's disease, non-Hodgkin's lymphoma, multiple myeloma, osteogenic sarcoma, Ewing's sarcoma, soft tissue sarcoma, neuroblastoma, rhabdomyosarcoma, Wilms' tumor, breast carcinoma, endometrial cancer, ovarian carcinoma, germ cell tumors, prostatic carcinoma, lung cancer, gastric carcinoma, head and neck cancer and thyroid carcinoma [1951769].

PREMARKETING

In March 2008, the drug was on the 'verge' of entering phase I/II trials [886749]. By June 2011, the company had planned to initiate phase I trials in the 'autumn' [1199190]; by October 2011, a phase I trial was expected to be initiated in the first quarter of 2012 [1246981]. In September 2012, data from a phase I trial were expected before the end of 2012 [1321659]. By January 2014, a phase I study was being planned [1532131].

In January 2007, clinical trials were expected to begin in the fourth quarter of 2007 [762402].

PRECLINICAL

By November 2002, in vivo studies were underway at Uppsala University [754834].

In November 2002, data were published from an in vitro study of doxorubicin formulated in a vehicle containing N-docosahexaenoyl-O-phospho-2-aminoethanol (C4) and N-all trans-retinoyl-O-phospho-L-tyrosine (C11). The formulation was tested in a panel of human tumor cell lines, 19 primary cultures of human tumor cells and 5 lymphocyte preparations. C4/C11 contributed significantly to the drug's toxicity; however, the EC50 values were lower for doxorubicin than for C4/C11 [754834].

ADDITIONAL INFORMATION

XR-17 consists of two isomeric retinoyl derivatives which can encapsulate doxorubicin to make it water soluble.

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DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country/ Territory	Development Status	Date
Oasmia Pharmaceutical AB	Neuroblastoma	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Soft tissue sarcoma	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Ovary tumor	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Germ cell and embryonic cancer	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Acute lymphoblastic leukemia	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Nephroblastoma	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Ewing sarcoma	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Hodgkins disease	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Breast tumor	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Osteosarcoma	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Acute myelogenous leukemia	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Thyroid tumor	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Endometrioid carcinoma	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Prostate tumor	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Multiple myeloma	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Non-Hodgkin lymphoma	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Rhabdomyosarcoma	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Chronic leukemia	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Lung tumor	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Stomach tumor	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Head and neck tumor	Russian Federation	Registered	08-Aug-2017
Oasmia Pharmaceutical AB	Cancer	Sweden	Preclinical	30-Nov-2002
Hetero Group	Non-Hodgkin lymphoma	Russian Federation	Discovery	08-Aug-2017

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Company	Indication	Country/ Territory	Development Status	Date
Hetero Group	Chronic leukemia	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Neuroblastoma	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Thyroid tumor	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Germ cell and embryonic cancer	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Ovary tumor	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Ewing sarcoma	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Hodgkins disease	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Nephroblastoma	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Multiple myeloma	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Breast tumor	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Prostate tumor	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Rhabdomyosarcoma	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Endometrioid carcinoma	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Stomach tumor	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Osteosarcoma	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Acute lymphoblastic leukemia	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Lung tumor	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Soft tissue sarcoma	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Acute myelogenous leukemia	Russian Federation	Discovery	08-Aug-2017
Hetero Group	Head and neck tumor	Russian Federation	Discovery	08-Aug-2017
Oasmia Pharmaceutical AB	Cancer	Azerbaijan	No Development Reported	04-Jun-2017
Oasmia Pharmaceutical AB	Cancer	Belarus	No Development Reported	04-Jun-2017
Oasmia Pharmaceutical AB	Cancer	Moldova, Republic of	No Development Reported	04-Jun-2017
Oasmia Pharmaceutical AB	Cancer	Uzbekistan	No Development Reported	04-Jun-2017
Oasmia Pharmaceutical AB	Cancer	Armenia	No Development Reported	04-Jun-2017

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Company	Indication	Country/ Territory	Development Status	Date
Oasmia Pharmaceutical AB	Cancer	Kazakhstan	No Development Reported	04-Jun-2017
Oasmia Pharmaceutical AB	Cancer	Tajikistan	No Development Reported	04-Jun-2017
Oasmia Pharmaceutical AB	Cancer	Kyrgyzstan	No Development Reported	04-Jun-2017

HISTORICAL DEVELOPMENT STATUS

Company	Indication	Country/ Territory	Development Status	Date
Oasmia Pharmaceutical AB	Cancer	Russian Federation	Pre-registration	04-Jan-2016
Oasmia Pharmaceutical AB	Cancer	Azerbaijan	Pre-registration	04-Jan-2016
Oasmia Pharmaceutical AB	Cancer	Belarus	Pre-registration	04-Jan-2016
Oasmia Pharmaceutical AB	Cancer	Kazakhstan	Pre-registration	04-Jan-2016
Oasmia Pharmaceutical AB	Cancer	Kyrgyzstan	Pre-registration	04-Jan-2016
Oasmia Pharmaceutical AB	Cancer	Moldova, Republic of	Pre-registration	04-Jan-2016
Oasmia Pharmaceutical AB	Cancer	Tajikistan	Pre-registration	04-Jan-2016
Oasmia Pharmaceutical AB	Cancer	Uzbekistan	Pre-registration	04-Jan-2016
Oasmia Pharmaceutical AB	Cancer	Armenia	Pre-registration	04-Jan-2016

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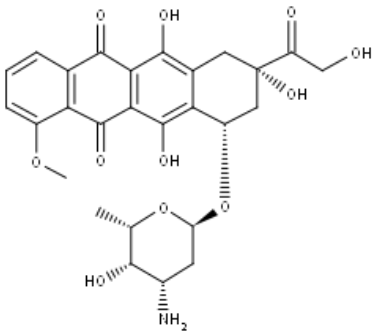
CHEMICAL STRUCTURES

Confidence Level: 1



Name	Type
doxorubicin	USAN; BAN; INN
Doxil	Trade Name
MCC-465	Research Code
CD-103	Research Code
LC-100	Research Code
DOX-003	Research Code
SP-1049C	Research Code
JIN-2019	Research Code
Livatag	Trade Name
GL-249	Research Code
Eos-001	Research Code
SA-033	Research Code
BOT-161	Research Code
QR-212	Research Code
Eos-003	Research Code
SPARC-08-038	Research Code
TLD-1	Research Code
Talidox	

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