
Vaccines and Diagnostics

The Novartis Vaccines and Diagnostics Division provides more than 20 products to fight vaccine-preventable viral and bacterial diseases, as well as sophisticated equipment to test blood donations for infections. The World Health Organization (WHO) considers vaccines to be the most cost-effective healthcare intervention available today.

Leader in vaccines and blood-testing equipment

Novartis formed this division as a strategic growth platform following the acquisition of Chiron Corporation in 2006.

The division consists of two businesses:

- Vaccines, which is focused on creating products to prevent influenza, meningitis and other diseases.
- Blood testing, which is dedicated to preventing the spread of infectious diseases through the development of novel blood-screening tools.

Vaccines

The current portfolio includes vaccines to prevent influenza, meningitis, rabies, Japanese encephalitis, tick-borne encephalitis, Haemophilus influenzae type B (Hib), polio, diphtheria, tetanus and pertussis (whooping cough).

Influenza

Every year, an estimated 3 million to 5 million people worldwide become seriously ill from influenza, and as many as 500 000 people – primarily children and the elderly – die from the ensuing complications. Novartis was the first vaccines company to enhance the efficacy of an influenza vaccine through the use of an adjuvant. Adjuvants are substances added to vaccines to enhance the body's immune response and are particularly important for the elderly or people with weakened immune systems. *Fluad*, an influenza vaccine containing the MF59-adjuvant, which is available in certain European countries, has been used safely and effectively for more than 10 years. Two of Novartis' A(H1N1) pandemic vaccines (*Focetria* and *Celtura*) are adjuvanted with MF59, which has antigen-sparing and cross-protection attributes.

Leader in influenza vaccines and pandemic response

During 2009, Novartis worked closely with governments and regulatory officials worldwide to tackle the A(H1N1) pandemic.

Novartis was the first company in the world to produce a batch of pandemic vaccine, announced the day after the WHO officially declared a pandemic on June 11, 2009. Novartis was the first company to have A(H1N1) pandemic vaccines licensed for use in both Europe and the US.

Novartis was also the first company to commercially develop and produce cell culture-based vaccines to prevent influenza. The *Optaflu* vaccine, based on novel cell-culture technology, instead of traditional egg-based production, showed that it is capable of producing an immune response at least as strong as the egg-based vaccine *Agrippal* (*Agriflu* in the US). Cell culture-based influenza vaccines offer advantages over egg-based production, including greater reliability and reduced production time. Novartis operates a cell culture-based manufacturing plant in Marburg, Germany, and is currently building a new cell culture-based manufacturing site in the United States in Holly Springs, North Carolina. *Celtura*, one of the A(H1N1) vaccines successfully marketed by Novartis to tackle the pandemic in 2009, is a cell culture-based vaccine.

First company to commercially produce cell-culture-based vaccines to prevent influenza

Meningitis

Meningococcal meningitis is a devastating disease with high public awareness. An estimated 500 000 cases of meningococcal disease occur every year, leading to some 50 000 premature deaths. In the past decade, Novartis has demonstrated its leadership in the meningitis area in the battle against meningococcal C infection through vaccination campaigns in the United Kingdom, Ireland, Canada, Australia and Spain. Our meningococcal C conjugate vaccine *Menjugate* has helped reduce the incidence of the meningococcal C disease in the United Kingdom by 87% and led to a reduction of more than 90% in the number of deaths caused by this bacterial infection. In addition, Novartis was the first company to develop and commercially distribute a meningitis B vaccine, targeting a specific strain endemic in New Zealand in a campaign that began in 2004. Data from the vaccination campaign showed that *MeNZB* has 80% efficacy in preventing cases of the New Zealand strain of meningococcal B disease.

Leader in meningitis vaccines

Menveo (ACWY-CRM conjugate vaccine) was discovered using glycoconjugation and in 2009 was recommended for approval in the EU for active immunization of adolescents from 11 years of age and adults at risk of exposure to *Neisseria meningitis* groups A, C, W135 and Y to prevent invasive disease.

Regulatory review for *Menveo* by the US Food and Drug Administration is ongoing.

Novartis also pioneered the use of reverse vaccinology to identify a candidate vaccine to prevent meningitis B (MenB) infections. Reverse vaccinology uses the sequencing of the genome to tackle pathogens that are difficult to target using traditional methods, and can reduce the time it takes to discover vaccine candidates from decades to years. The MenB vaccine is in Phase III clinical development, having shown excellent immunogenicity in both infants and adults in Phase II trials. Regulatory submissions for the Novartis MenB vaccine are planned for 2010.

MenB vaccine: excellent immunogenicity in both infants and adults

Pediatric vaccines

Through partnerships with the WHO, UNICEF and other organizations, Novartis delivers hundreds of millions of vaccine doses every year to help protect children from diseases such as diphtheria, tetanus and polio. The *Polioral* polio vaccine is part of the global campaign to eradicate this disease.

Novartis partners with WHO, UNICEF to deliver hundreds of millions of vaccine doses

Adult and traveler vaccines

Novartis produces some of the world's most widely used vaccines against rabies and tick-borne encephalitis, diseases of particular concern to travelers. *Ixiaro*, a new vaccine for the prevention of Japanese encephalitis, was launched in 2009 in the US, EU and other international markets following marketing approvals in the United States and the European Union. *Ixiaro* is part of the strategic alliance between Novartis and Intercell AG.

Some of the world's most widely used vaccines

A promising pipeline

Novartis is a leader in traditional and novel research approaches, and has an early-stage pipeline focusing on unmet medical needs such as the prevention of *Helicobacter pylori* infections, a major cause of gastritis that can lead to gastric ulcers and gastric cancer. Several vaccine candidates have the potential of being first in their category to reach the market.

Leader in traditional and novel research approaches

Blood testing

It is vitally important to screen blood because a single unit of whole blood collected from an infected donor may be transfused into up to four recipients or added to pools of more than 1 000 units to manufacture blood-derived products.

Leader in blood safety

A leader in blood safety since 1986, scientists at Chiron first identified the hepatitis C (HCV) virus, leading to the development of the first test to screen blood for this virus. Today, the business is dedicated to preventing transfusion-transmitted diseases, and Novartis Diagnostics now provides products to test blood donations for HIV (the AIDS virus), HCV, hepatitis B and West Nile Virus.

Preventing transfusion-transmitted diseases

Advanced instruments, training, software and assays are provided to blood centers and laboratories worldwide to target a variety of infectious agents. The *Procleix* Assays and Systems incorporate state-of-the-art nucleic acid testing (NAT) technology, developed by Gen-Probe Inc., to detect viral RNA and DNA in donated blood, plasma, organs and tissue. By identifying infectious agents during the very early stages of infection, *Procleix* products help blood centers prevent transfusion-related infections. The *Procleix* TIGRIS system is a high-throughput instrument offering fully automated testing. During 2009, the *Procleix UltrioPlus* system was introduced in selected markets worldwide.

Advanced support for targeting infectious agents

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