

## 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:

- Novartis Vaccines is focused on creating products to prevent influenza, meningitis and other diseases.
- Blood testing, which retains the Chiron name, 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.

First adjuvanted influenza vaccine

Novartis is 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*. Cell-culture-based influenza vaccines offer advantages over egg-based production, including greater

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

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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.

### *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 conducted in partnership with the New Zealand Ministry of Health showed that *MenZB* has 80% efficacy in preventing cases of the New Zealand strain of meningococcal B disease. *Menveo* (ACWY-CRM conjugate vaccine) was discovered using glycoconjugation and has shown strong clinical data in Phase III trials. In 2008 both the US and EU submissions for *Menveo* were completed.

Leader in meningitis vaccines

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 now 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 for infants and children are planned for 2010.

MenB vaccine: excellent immunogenicity in both infants and adults

### *Pediatric vaccines*

Through partnerships with the World Health Organization (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

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### *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, has been submitted for marketing approval 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 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. A new research site in Cambridge, Massachusetts, was opened in September 2008 for up to 250 scientists as a global center of excellence in viral vaccine discovery.

Global center of excellence in viral vaccine discovery

### **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

Chiron has been a leader in blood safety since 1986, when Chiron scientists 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 Chiron now provides products to test blood donations for HIV (the AIDS virus), HCV, hepatitis B and West Nile Virus.

Preventing transfusion-transmitted diseases

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Chiron produces advanced instruments, training, software and assays targeting a variety of infectious agents to blood centers and laboratories worldwide. 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.

Advanced support for  
targeting infectious agents

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