

Major Developments in 2009

January

The US Department of Health and Human Services (HHS) awards Novartis a USD 486 million contract to build the first US facility to manufacture cell-based vaccine for seasonal and pandemic flu. The facility, which will be completed in 2012, will have the capacity to manufacture 150 million doses of pandemic vaccine within six months of declaration of an influenza pandemic.

US government awards
Novartis contract to build
pandemic vaccine facility

Japan approves four Novartis medicines for cancer, asthma, high blood pressure and “wet” age-related macular degeneration. They are *Tasigna*, *Xolair*, *Co-Diovan*, and *Lucentis*.

Novartis Japan receives
approval of four innovative
medicines

Novartis launches *Extavia*, a new branded version of interferon beta-1b, to help patients combat the devastating symptoms of multiple sclerosis (MS). The new therapeutic option launches initially in Germany and Denmark with other European launches to follow during 2009.

Novartis launches *Extavia*
for the treatment of MS

Novartis and Medicines for Malaria Venture launch *Coartem* Dispersible, the first artemisinin-based combination therapy developed for children suffering from malaria. The easy-to-administer formulation can help improve treatment and compliance among children who account for a vast majority of malaria-related deaths.

Novartis and Medicines
for Malaria Venture launch
Coartem Dispersible

Novartis successfully launches major bond market transaction, issuing a two-tranche bond with a total size of USD 5 billion that has been registered in the US.

Novartis launches
USD 5 billion bond issue

February

Novartis gains the exclusive worldwide rights to elinogrel, a promising anti-clotting agent in Phase II clinical trials that has shown potential to offer clinical improvements over current anti-clotting medications in helping patients avoid heart attacks and strokes. As part of the agreement with Portola Pharmaceuticals, Inc., Novartis will have responsibility for the Phase III development, manufacturing and commercialization of elinogrel, which is being developed as oral and intravenous formulations.

Novartis gains worldwide
rights to elinogrel

Sandoz receives European Commission (EC) approval for biosimilar filgrastim, paving the way for this oncology medicine to be made available to patients across the EU. Filgrastim is a natural protein produced commercially by recombinant DNA technology, which stimulates production of white blood cells.

EC approves Novartis
biosimilar filgrastim

March

Novartis makes tender offer to acquire an additional stake in its majority-owned Indian subsidiary, Novartis India Ltd., from public shareholders. The offer would raise the stake of Novartis in its Indian subsidiary to nearly 90% from the current level of 50.9%. The offer represents a total value of up to Rs 4.4 billion (or approximately USD 87 million).

Novartis makes offer to increase stake in Novartis India Ltd.

The United States Food and Drug Administration (US FDA) approves *Afinitor* tablets for patients with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib. The approval is based on data that shows *Afinitor*, when compared with placebo, more than doubled the time without tumor growth or death in patients with advanced kidney cancer (4.9 vs. 1.9 months) and reduced the risk of disease progression or death by 67%.

US FDA approves *Afinitor*

Ixiaro vaccine receives US FDA approval for the prevention of Japanese Encephalitis, a mosquito-borne disease that results in 10 000-15 000 deaths annually and is a potential threat for travelers to Asia. *Ixiaro* was developed by Intercell AG. Novartis and Intercell have a strategic alliance that provides Novartis with the commercialization rights to *Ixiaro*.

US FDA approves *Ixiaro*

The EC grants marketing authorization to *Ixiaro* vaccine for the prevention of Japanese Encephalitis.

EC grants marketing authorization to *Ixiaro*

April

The US FDA approves *Coartem*, the leading artemisinin-based combination treatment (ACT) for malaria worldwide. *Coartem* is a highly-effective three-day malaria treatment with cure rates of over 96% even in areas of multi-drug resistance. Each year millions of Americans travel to malaria-endemic regions on business or pleasure, and this has led to a rise in cases of “travelers malaria.” Unlike patients in more than 80 countries, US patients have not had access to ACTs like *Coartem*.

US FDA approves *Coartem*

Exforge HCT receives US FDA approval. It is the only single pill to combine the three most prescribed high blood pressure treatments in their classes in the US, providing a new option for patients who have tried taking dual combinations of these classes of blood pressure medications without success.

US FDA approves *Exforge HCT*

The EC approves *Gleevec/Glivec* as the first and only treatment available in Europe to reduce the risk of recurrence in adult patients who are at significant risk of relapse following surgery to remove gastrointestinal stromal tumors (GIST).

EC approves *Gleevec/Glivec* as first post-surgery therapy to reduce risk of recurring GIST

May

Novartis announces that Jon Symonds, a Managing Director, Investment Banking, at Goldman Sachs, will be joining Novartis on September 1 as deputy CFO and as CFO designate, reporting to Raymund Breu, who will retire on March 31, 2010 after 35 years of outstanding service to Novartis.

Novartis names deputy CFO and CFO designate

Novartis announces that it has entered into an agreement with the Takeda Pharmaceutical Company in Japan for the distribution of the Novartis *Vaxem-Hib* vaccine for the prevention of infection caused by *Haemophilus influenzae* type B (Hib). Through this agreement, Novartis will manufacture the vaccine and supply it to Takeda, which will obtain exclusive rights to license, market and distribute the vaccine in Japan.

Novartis announces it will enter Japan vaccines market

The US FDA approves *Reclast/Aclasta* for the prevention of osteoporosis in postmenopausal women for two years with a single dose. The FDA decision is based on a study involving more than 500 postmenopausal women with osteopenia, or low bone mass, showing that a single infusion of *Reclast/Aclasta* significantly increased bone mineral density (BMD) at two years compared to placebo.

US FDA approves *Reclast/Aclasta* for the prevention of osteoporosis in postmenopausal women with less frequent dosing

June

Novartis successfully launches a notes issue of EUR 1.5 billion with a coupon of 4.25% under its EUR 15 billion Euro Medium Term Note Programme. Proceeds will be used for general corporate purposes.

Novartis launches EUR 1.5 billion notes issue

The US FDA has approved *Ilaris* for the treatment of children and adults with cryopyrin-associated periodic syndrome (CAPS), which includes a number of rare but life-long auto-inflammatory disorders with debilitating symptoms and limited treatment options. The FDA granted priority review to *Ilaris* based on its potential to meet an important clinical need for patients with CAPS.

US FDA approves *Ilaris*

Sandoz receives marketing authorization for the first-ever Japanese biosimilar, recombinant human growth hormone somatropin. The precedent-setting decision further reinforces Sandoz's global leadership position in the rapidly-emerging market for biosimilars, or follow-on versions of existing state-of-the-art biopharmaceuticals.

Sandoz receives approval for first-ever Japanese biosimilar, somatropin

Novartis announces the delivery of the 250 000 000th treatment of *Coartem*, a highly-effective artemisinin-based combination therapy (ACT) for the treatment of malaria, with cure rates of more than 95%. Reinforcing Novartis' long-term commitment to patients in the developing world, Dr. Daniel Vasella, Novartis Chairman and CEO, also announces that Novartis is the first healthcare company to join United Against Malaria, a consortium that strives to raise awareness of malaria and achieve the shared goal of ending malaria deaths in Africa by 2015.

Novartis delivers the 250 000 000th treatment of *Coartem*

July

Novartis announces the extension of its tuberculosis (TB) drug donation to Tanzania, where it has already delivered nearly 250 000 TB treatments between 2005 and 2008. Novartis committed to extend the donation, delivering another 250 000 treatments over the next three to four years. This donation is worth about USD 6 million and aimed to treat an estimated 60 000 patients per year.

Novartis extends TB drug donation to Tanzania

The Japanese Ministry of Health, Labor and Welfare approves *Tekturna/Rasilez*, a first-in-class direct renin inhibitor (DRI), for the treatment of high blood pressure. *Rasilez* (known as *Tekturna* in the US), can be used alone or in combination with other high blood pressure medicines.

Japanese Ministry of Health approves *Tekturna/Rasilez*

The US FDA approves *Tekturna HCT* tablets as an initial therapy for patients who are likely to need multiple drugs to achieve their blood pressure goals. *Tekturna HCT* is a single-pill combination of *Tekturna/Rasilez*, the first and only approved direct renin inhibitor, and the diuretic hydrochlorothiazide, one of the most commonly used high blood pressure medications.

US FDA approves *Tekturna HCT*

August

The EC approves *Afinitor* tablets for the treatment of patients with advanced renal cell carcinoma (RCC) whose disease progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy. Prior to *Afinitor*, there were no proven treatment options for advanced RCC patients whose cancer progressed while on or after treatment with VEGF-targeted therapy.

EC approves *Afinitor*

Sandoz is the first and only company in the US to launch generic tacrolimus capsules, a generic equivalent of Prograf[®]. Tacrolimus is an immunosuppressive treatment used to help prevent rejection of a kidney or liver transplant.

Sandoz launches first generic version of Prograf[®] capsules

US FDA approves *Extavia*, the first in a new portfolio of planned MS therapies from Novartis to help patients with this devastating disease. The same medicinal product as Betaseron[®], *Extavia* offers patients and physicians a new branded version of interferon beta-1b, a first-line disease-modifying therapy that has been a standard-of-care for MS in the US for more than 16 years.

US FDA approves *Extavia*

Novartis receives US FDA approval for *Valturna*, a single-pill combination of valsartan and aliskiren, to treat high blood pressure. This is the first approval for *Valturna*, which is indicated for the treatment of high blood pressure in patients not adequately controlled on aliskiren or angiotensin receptor blocker (ARB) monotherapy and as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.

US FDA approves *Valturna*

September

Sandoz announces that it has completed its USD 1.3 billion acquisition of EBEWE Pharma's specialty generic injectables business, paving the way for the creation of a global center of excellence in generic oncology injectables. The transaction offers Sandoz, the world's second largest generics company, a complementary portfolio of differentiated generics, with more than 15 marketed products and a strong pipeline with several near-term launches.

Sandoz completes acquisition of EBEWE Pharma

Novartis announces that *Focetria*, the Novartis Influenza A(H1N1) 2009 monovalent vaccine, has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The positive opinion clears the way for European Union approval in all 27 Member States as well as in Iceland and Norway.

Novartis A(H1N1) Pandemic Influenza vaccine *Focetria* receives positive opinion from CHMP

Sandoz launches somatropin, the first-ever Japanese biosimilar, increasing access to key medicines in the second largest global market. The launch follows the precedent-setting approval of somatropin – already marketed as *Omnitrope* in the EU, US, Australia and elsewhere – by Japan's Ministry of Health, Labor and Welfare (MHLW) in June 2009.

Sandoz launches somatropin in Japan

October

Novartis gains exclusive worldwide rights to market PTK796, potentially the first once-daily broad-spectrum antibiotic that can be given by intravenous (IV) infusion or oral tablet to treat a wide variety of life-threatening infections, including those caused by highly resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA) and multi-drug resistant *Streptococcus pneumoniae* (MDRSP). Under the agreement with Paratek Pharmaceuticals, the companies will share responsibility for developing PTK796.

Novartis gains exclusive worldwide rights to market PTK796

Novartis Pharma AG announces that it has entered into an agreement for exclusive US and Canadian commercialization rights to *Fanapt*, a new oral medication that is approved by the US FDA for the acute treatment of adults with schizophrenia. Novartis plans to launch *Fanapt* in the US in early 2010. As part of the agreement with Vanda Pharmaceuticals Inc., Novartis will also have exclusive rights to develop and commercialize a long-acting injectable (or "depot") formulation of this medicine for these markets.

Novartis gets exclusive US and Canadian commercialization rights to *Fanapt*

The EC grants Novartis marketing authorization for *Exforge HCT*, a new 3-in-1 treatment for people with high blood pressure. *Exforge HCT* combines in a once-daily single pill the efficacy of three widely prescribed blood pressure medications: the angiotensin receptor blocker valsartan (*Diovan*), the calcium channel blocker amlodipine, and the diuretic hydrochlorothiazide (HCT).

Novartis receives approval in the EU for *Exforge HCT*

Novartis' biological drug *Ilaris* gets approval in the EU to treat children and adults with CAPS, a rare debilitating auto-inflammatory disease. The accelerated EU decision follows approvals in the US and Switzerland, where *Ilaris* was granted priority review in view of the significant unmet medical need. *Ilaris* is the only medicine approved in the EU for CAPS patients as young as four years old, and for patients with the most debilitating form of CAPS, neonatal-onset multisystem inflammatory disease.

Ilaris gets approval in the EU

Novartis announces a USD 1 billion investment over the next five years, increasing R&D activities in China and confirming Novartis' long term commitment to China's further economic development, health reform and improving the health care of the Chinese people. The Novartis investment will include a significant expansion of The Novartis Institute of BioMedical Research in Shanghai.

Novartis announces USD 1 billion investment to build largest pharmaceutical R&D institute in China

November

Novartis reaches an agreement to acquire an 85% stake in the Chinese vaccines company Zhejiang Tianyuan Bio-Pharmaceutical Co., Ltd. as part of a strategic initiative to build a vaccines industry leader in China and expand the Group's limited presence in this fast-growing market segment. Zhejiang Tianyuan offers a range of marketed vaccine products in China and R&D projects for various preventable viral and bacterial diseases.

Novartis expands human vaccines presence in China by acquiring stake in Zhejiang Tianyuan

Novartis launches *Prevacid24HR* over-the-counter (OTC) in pharmacies and retail stores across the US to treat frequent heartburn for a full 24 hours with one pill a day. It is the first and only OTC Proton Pump Inhibitor (PPI) for the treatment of frequent heartburn in its original formulation.

Novartis launches *Prevacid24HR* over-the-counter

Celtura, Novartis' adjuvanted cell culture-based Influenza A(H1N1) 2009 monovalent vaccine, receives approval in Switzerland from Swissmedic, the Swiss Agency for Therapeutic Products. This is the second marketing approval for the cell culture-based A(H1N1) pandemic vaccine in Europe.

Novartis receives approval in Switzerland for *Celtura*

Novartis gains exclusive rights to two oral targeted investigational therapies focusing on patients with life-threatening blood disorders and cancers that currently do not have effective treatment options. Under a licensing agreement with Incyte Corporation, Novartis will have responsibility for the future development of Incyte's investigational JAK inhibitor outside the US and for future development of an early-stage cMET inhibitor globally.

Novartis gains rights to two oral targeted investigational therapies

Novartis receives approval in the EU for *Onbrez Breezhaler*, a new once-daily maintenance bronchodilator for the treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). COPD impairs lung function resulting in chronic breathlessness.

EC approves *Onbrez Breezhaler*

December

Tasigna Phase III clinical trial shows superior results to *Gleevec/Glivec* in adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase. In the first head-to-head comparison of these two oral therapies as initial treatment for this life-threatening blood cancer, *Tasigna* results showed statistically significant improvement over *Gleevec/Glivec* in every measure of efficacy.

Tasigna trial shows superior results to *Gleevec/Glivec* in patients with early-stage chronic myeloid leukemia

Novartis is set to sustain its leading global position in oncology with a portfolio of 16 new molecular entities focused on various life-threatening diseases. Plans include regulatory submissions by the end of 2009 to expand the use of the marketed products *Tasigna* and *Zometa* for treatment of various cancers. Up to five other regulatory submissions are possible in 2010 involving *Afinitor* and other development compounds based on the outcome of ongoing clinical trials in various tumor types.

Novartis to sustain leading global position in Oncology with strong portfolio

Menveo receives a Positive Opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The investigational conjugate vaccine is recommended for active immunization of adolescents (from 11 years of age) and adults at risk of exposure to *Neisseria meningitidis* groups A, C, W135 and Y, to prevent invasive disease. *Menveo* is designed to help protect against four of the five major groups of meningococcal bacteria, which are leading causes of bacterial meningitis, an infection of the membrane around the brain and spinal cord, and sepsis, a bloodstream infection.

Menveo receives recommendation for approval in the EU

The World Health Organization (WHO) grants prequalification for all three of Novartis' Influenza A(H1N1) 2009 monovalent vaccines for supply to United Nations agencies: the cell culture-based and MF59 adjuvanted vaccine *Celtura*, the egg-based and MF59 adjuvanted vaccine *Focetria* as well as the egg-based A(H1N1) vaccine manufactured using the seasonal *Fluvirin* platform. In addition to granting prequalified status for Novartis' three Influenza A(H1N1) 2009 vaccines, WHO also granted prequalification for the company's trivalent seasonal *Fluvirin* vaccine.

WHO prequalifies three Novartis A(H1N1) 2009 influenza vaccines for use in developing world

Novartis announces that it will gain exclusive worldwide rights to relaxin, a recombinant version of a naturally occurring human peptide, through the acquisition of the privately held US biopharmaceutical company Corthera Inc. Relaxin is currently in

Novartis to acquire Corthera Inc. and gain worldwide rights to Phase III project relaxin

Phase III clinical trials as a potential treatment option for patients with acute decompensated heart failure (ADHF).

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