

## Major developments in 2008

### January

*Tekturna HCT* is approved by the US Food and Drug Administration (FDA) as a single-tablet combination of two high blood pressure medicines: *Tekturna*, the first new type of high blood pressure medicine in more than a decade, and the diuretic hydrochlorothiazide (HCT).

*Tekturna HCT* approved by US FDA

### February

*Galvus* is approved by European health authorities as a new oral treatment for type 2 diabetes patients, paving the way for launches in Europe. This regulatory approval applies in all 27 countries of the European Union as well as in Norway and Iceland.

*Galvus* – new oral treatment for type 2 diabetes – approved in Europe

Novartis announces the opening of a new vaccines research institute in Siena, Italy, with a nonprofit mission to exclusively focus on the development of vaccines for diseases of the developing world. The Novartis Vaccines Institute for Global Health (NVGH) is the first institute of its kind to be set up by a major vaccines manufacturer.

Novartis opens nonprofit vaccines institute focused on diseases of the developing world

### March

*Omnitrope* Pen 5 with a liquid cartridge is introduced in the United States by Sandoz, priced 35% below the originator product. The launch enhances patient access to this biosimilar, a follow-on version of a previously approved recombinant biotechnology drug. *Omnitrope* is indicated for long-term treatment of pediatric patients who have growth failure and long-term replacement therapy in adults with growth hormone deficiency.

*Omnitrope* Pen 5 introduced in US

### April

Novartis reaches an agreement with Nestlé S.A. offering Novartis the right to acquire majority ownership of Alcon Inc., the world leader in eye care with pharmaceutical, surgical and consumer products. The first step was completed in July 2008 by purchasing a 25% stake from Nestlé. An optional second step provides future rights for Novartis to acquire, and Nestlé to sell, the remaining 52% stake held by Nestlé between January 2010 and July 2011.

Agreement to acquire majority ownership of Alcon Inc.

Novartis reduces the price of *Coartem* tablets, the state-of-the-art artemisinin-based combination treatment (ACT) for malaria, by 20% on average. The price reduction, launched on World Malaria Day, is made possible through efficiency gains in the production of *Coartem*.

Efficiency gains reduce cost of antimalaria treatment

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## May

New data show *Afinitor* (everolimus/RAD001) may provide an important new treatment option for patients with advanced kidney cancer who have failed standard therapies. The RECORD-1 trial shows *Afinitor* reduces risk of disease progression by 70%. Once-daily oral *Afinitor* directly targets and continuously inhibits mTOR, a protein that controls cell division and blood vessel growth.

New data show *Afinitor* may provide treatment option for advanced kidney cancer

## June

Novartis unveils a promising pipeline of novel vaccines, highlighting vaccine candidates that address significant unmet needs for prevention of fatal diseases such as meningococcal infections as well as hospital- and community-acquired infections. Several vaccine candidates from the Novartis Vaccines research and development portfolio have the potential of being the first of their kind.

Promising pipeline of novel vaccines unveiled

Novartis signs a definitive agreement to acquire Protez Pharmaceuticals along with the rights in North America and Europe to PTZ601, a novel antibiotic in clinical development for treatment of hospital-acquired infections.

Agreement to acquire Protez Pharmaceuticals

*Reclast* Injection 5 mg is approved for the prevention of new clinical fractures in patients who have recently had a low-trauma hip fracture, following the US FDA's decision to broaden US indications of this once-yearly injection.

## July

Novartis announces the purchase of an additional 51.7% stake in Swiss biotechnology company Speedel Holding Ltd., through off-exchange transactions together with plans to buy all remaining shares in a mandatory public tender offer completed in September 2008, securing access to a portfolio of innovative hypertension treatments.

Purchase of additional stake in Speedel Holding Ltd.

Novartis announces a unique and flexible long-term partnership with Lonza, a global biotechnology leader in process development and manufacturing, to rapidly scale up technical development and clinical production for part of the rapidly growing Novartis biologics pipeline.

Long-term partnership with Lonza announced

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## August

*Diovan HCT* and *Exforge*, two single-pill combination medications, are approved by the US FDA as initial or first-line therapies in patients likely to need multiple drugs to achieve their blood pressure goals.

Two medications approved by US FDA as first-line therapies for blood pressure

## September

*Omnitrope* Pen 10 with liquid cartridge receives US FDA approval. The Sandoz product is approved for long-term treatment of pediatric patients who have growth failure and long-term replacement therapy in adults with growth-hormone deficiency.

*Omnitrope* Pen 10 receives US FDA approval

## October

Imatinib shows promising results in an early proof-of-concept study for the treatment of pulmonary arterial hypertension, a severe, incurable blood vessel disorder.

Novartis strengthens its capabilities for developing medicines that can be delivered via the lungs through a definitive agreement to acquire the pulmonary drug-delivery business unit of Nektar Therapeutics.

Novartis acquires pulmonary drug-delivery business

## November

Novartis highlights the success of its pharmaceuticals research strategy in delivering novel compounds, reflecting the benefits of sustained investments in research and development. The exploratory pipeline advances with a 40% increase in the size of the portfolio of new molecular entities from 2005, and a 60% improvement in the transition of compounds from proof-of-concept to confirmatory clinical trials.

New molecular entities portfolio increases 40% versus 2005

*Rasilez HCT* receives a positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) recommending marketing authorization as a new treatment combination for high blood pressure.

Filgrastim, the third biosimilar medicine of Sandoz, receives a positive opinion from European regulators, marking another important milestone for the division in bringing affordable high-quality biopharmaceuticals to patients.

Third biosimilar from Sandoz recommended for approval in Europe

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## December

*Gleevec/Glivec* receives US FDA approval as the first treatment to reduce the risk of cancer returning in patients with gastrointestinal stromal tumors.

US FDA approves  
*Gleevec/Glivec* for  
treatment of gastro-  
intestinal stromal  
tumors

Novartis strengthens its vaccines pipeline through an exclusive agreement to license AlphaVax' investigational Cytomegalovirus vaccine program. This agreement adds to the promising early-stage pipeline of novel vaccines at Novartis.

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