

## Pharmaceuticals

The Pharmaceuticals Division of Novartis is recognized worldwide for the innovative medicines we provide to patients, physicians and healthcare organizations. This growing business develops and markets patent-protected prescription drugs for important health needs. Our products are concentrated in major therapeutic areas including:

- Cardiovascular and Metabolism
- Oncology (including Hematology and Molecular Diagnostics)
- Neuroscience and Ophthalmics
- Respiratory
- Immunology and Infectious Diseases

The current product portfolio includes more than 50 key marketed products, many of which are leaders in their respective therapeutic areas. In 2009, a total of 25 positive regulatory decisions were received in the United States, Europe and Japan.

The product development pipeline has 145 projects in various stages of clinical development, including potential new products as well as potential new indications or formulations for existing products.

### Key marketed products

***Afinitor*** (everolimus) is an oral inhibitor of the mTOR pathway. It was launched in March 2009 in the US following regulatory approval as the first therapy for patients with advanced renal cell carcinoma (advanced kidney cancer) after failure of treatment with sunitinib or sorafenib. European regulatory approval was received in August 2009; Swiss approval was received in November 2009; Canadian approval in November 2009; and Japanese approval in January 2010. Positive early data show potential for RAD001 (*Afinitor*) in breast cancer, gastric cancer, hepatocellular carcinoma, lymphoma and pancreatic neuroendocrine tumors. RAD001 is being studied in many cancer types. Enrollment has been completed in Phase III studies in neuroendocrine tumors (NET) with results expected in 2010. Phase III studies are underway in breast cancer, lymphoma, gastric cancer and tuberous sclerosis complex (TSC). A pivotal study in liver cancer is planned. Everolimus, the active ingredient in *Afinitor*, is also available outside of the US under the brand name *Certican* for use in transplantation.

Innovative products in five major therapeutic areas

Strong pipeline of new medicines to help drive future growth

A therapy for patients with advanced kidney cancer

---

**Certican** (everolimus) is an mTOR inhibitor and immunosuppressive drug for the prevention of organ rejection in adult patients at low-to-moderate immunological risk receiving a kidney or heart transplant. First launched in 2003, everolimus is marketed in more than 70 countries. In 2008, Phase III development was initiated worldwide for the prevention of organ rejection in liver transplantation. In the US, everolimus is in registration for the prevention of organ rejection in kidney transplantation under the brand name *Zortress*. Everolimus, the active ingredient in *Certican/Zortress*, is also available under the brand name *Afinitor* for an oncology indication.

Immunosuppressive drug for the prevention of organ rejection

**Comtan, Stalevo** (carbidopa, levodopa and entacapone) are indicated for the treatment of certain Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations known as "wearing off." *Stalevo* was approved in the US and EU in 2003, and is available in more than 50 countries. *Comtan* (entacapone) is marketed in approximately 50 countries under a licensing agreement with Orion. *Stalevo* and *Comtan* were developed and are manufactured by the Orion Corporation, and are marketed by Novartis and Orion in their respective territories.

A treatment for Parkinson's disease patients with end-of-dose "wearing-off" symptoms

**Diovan** (valsartan), together with **Diovan HCT/Co-Diovan** (valsartan and hydrochlorothiazide), is the number one selling hypertension medication worldwide. *Diovan* is the only agent in its class approved to treat all of the following: high blood pressure (including children aged six to 16 years in the US), high-risk heart attack survivors and patients with heart failure. The efficacy and safety profile of *Diovan* has been well established by a large body of evidence. *Diovan* inhibits a hormone, angiotensin II, from binding to a receptor that causes arteries to tighten and narrow, an action that can cause high blood pressure. The single-pill combination product *Co-Diovan* includes the diuretic hydrochlorothiazide and provides additional efficacy for patients needing a greater reduction in blood pressure. First launched in 1996, *Diovan* is available in more than 120 countries for treating high blood pressure, in more than 90 countries for heart failure, and in more than 70 countries for heart attack survivors. First launched in 1997, *Diovan HCT/Co-Diovan* is approved in more than 100 countries worldwide. In July 2008, the US FDA approved *Diovan HCT* for the first-line treatment of hypertension in patients unlikely to achieve blood pressure control on a single agent. In January 2009, *Co-Diovan* was approved for the treatment of high blood pressure in Japan.

Number one selling hypertension medication worldwide

---

**Exelon** (rivastigmine tartrate) is a therapy for mild to moderate Alzheimer's disease and dementia associated with Parkinson's disease. First approved in 1997, *Exelon* is available in more than 70 countries. In 2007, *Exelon Patch* (rivastigmine transdermal system), the only skin patch for mild to moderate Alzheimer's disease, was approved in the US and Europe. In certain countries it is also indicated for dementia associated with Parkinson's disease. *Exelon Patch* has now been launched in more than 60 countries.

Only skin patch approved for mild to moderate Alzheimer's disease

**Exforge** (valsartan and amlodipine besylate) is a single pill combination of the angiotensin receptor blocker *Diovan* (ARB) and the calcium channel blocker amlodipine besylate (CCB). First approved in Switzerland in 2006, and in the US and EU in 2007 for the treatment of high blood pressure, it is now approved in more than 90 countries and available in more than 70. In July 2008, the US FDA approved *Exforge* for the first-line treatment of hypertension in patients likely to need multiple drugs to achieve their blood pressure goals. Japanese approval was received in January 2010. *Exforge HCT* (valsartan, amlodipine besylate and hydrochlorothiazide) is a new single pill combining three widely prescribed high blood pressure treatments – ARB (valsartan), CCB (amlodipine) and HCT (hydrochlorothiazide). In April 2009, the US FDA approved *Exforge HCT* for patients who have tried taking dual combinations of these classes of drugs without success. In October 2009, *Exforge HCT* was also approved in the EU as substitution therapy for patients controlled on all three agents (individual or in combination).

First single-pill combination of the two number-one anti-hypertensives

**Exjade** (deferasirox) is an oral iron chelator approved for the treatment of chronic iron overload due to blood transfusions in patients who have a wide range of underlying anemias. Iron overload is a cumulative, potentially life-threatening consequence of frequent blood transfusions. Patients with congenital and acquired chronic anemias, such as thalassemia, sickle cell disease and myelodysplastic syndromes require transfusions as support for their anemia. *Exjade* was first approved in 2005 and is now approved in more than 90 countries, including the US, EU and Japan. Approval in China is anticipated in 2010.

First once-daily oral iron chelator approved to remove excess iron caused by blood transfusions in patients with wide range of underlying anemias

**Extavia** (interferon beta-1b) is an injectable disease-modifying therapy for relapsing forms of multiple sclerosis (MS). It is the Novartis brand of interferon beta-1b, a product also currently marketed by Bayer Healthcare Pharmaceuticals Inc. under the brand name Betaseron® in the US and by Bayer Schering Pharma under the brand name Betaferon® in the EU. *Extavia* was approved in the EU in May 2008 and since January 2009 has been launched in

Treatment for broad range of multiple sclerosis (MS) patients

---

more than 20 markets, including the US in September 2009. Additional launches are planned in 2010. *Extavia* represents the first entry of Novartis into the treatment of MS.

**Fanapt** (iloperidone) is a dopamine type 2 (D2) and serotonin type 2 (5-HT2A) receptor antagonist antipsychotic agent. *Fanapt* is indicated in the US for the acute treatment of schizophrenia in adults and was launched there in January 2010. Schizophrenia is a severe psychiatric disorder that is estimated to affect more than two million adults in the US. *Fanapt* belongs to a class of medication for schizophrenia known as atypical antipsychotics.

A new antipsychotic therapy for the acute treatment of adults with schizophrenia

**Femara** (letrozole tablets/letrozole) is a once-daily oral aromatase inhibitor for the treatment of early-stage or advanced breast cancer in postmenopausal women. First launched in 1996, *Femara* is currently available in more than 90 countries. *Femara* is approved in the US, EU and other countries as adjuvant therapy for postmenopausal women with hormone receptor-positive early breast cancer. It is also approved in the US, EU and other countries as extended adjuvant therapy for early breast cancer in postmenopausal women who are within three months of completing five years of adjuvant tamoxifen therapy. In addition, *Femara* is approved in the US, EU and other countries as first-line treatment for postmenopausal women with hormone receptor-positive locally advanced or metastatic breast cancer, and as a treatment for advanced breast cancer in postmenopausal women with disease progression following anti-estrogen therapy. In some countries, *Femara* is approved as neo-adjuvant (pre-operative) therapy for early stage breast cancer. In Japan, *Femara* is approved for the treatment of all hormone receptor-positive breast cancer in postmenopausal women.

Treatment of early-stage or advanced breast cancer in postmenopausal women

**Galvus** (vildagliptin), an oral treatment for type 2 diabetes, and **Eucreas**, a single-pill combination of vildagliptin and metformin, have achieved rapid success in many European, Latin American and Asia-Pacific markets since they were first launched in 2007. *Eucreas* was the first single-pill combination product including a DPP-4 inhibitor and another medication, metformin, to be launched in Europe. *Galvus* is currently approved in 70 countries, including Japan, and launched in 37 countries. *Eucreas* is currently approved in 50 countries and launched in more than 40 countries, including the EU, Latin America and Asia.

Oral treatments for type 2 diabetes patients

---

***Gleevec/Glivec*** (imatinib mesylate/imatinib) is a signal transduction inhibitor approved to treat certain forms of chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST). First launched in 2001, *Gleevec/Glivec* is available in more than 90 countries. It is one of the first oncology drugs that validates rational drug design based on an understanding of how some cancer cells work. A signal transduction inhibitor interferes with the pathways that stimulate the growth of tumor cells. *Gleevec/Glivec* is indicated for the treatment of newly diagnosed adult and pediatric patients with a form of CML. *Gleevec/Glivec* is approved in the US, EU and Japan to treat Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL), a rapidly progressive form of leukemia; dermatofibrosarcoma protuberans, a rare solid tumor; hypereosinophilic syndrome and myelodysplastic/myeloproliferative diseases; and other rare blood disorders. In the US, *Gleevec/Glivec* is also approved for aggressive systemic mastocytosis. *Gleevec/Glivec* received EU and Swiss regulatory approval in 2009 as a post surgery (adjuvant setting) therapy for GIST following the US approval in 2008. The *Gleevec/Glivec* International Patient Assistance Program is now available in 80 countries and is currently providing access to *Gleevec/Glivec* for free to more than 37 000 patients worldwide through this innovative program.

Treatment for certain forms of chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST)

***Ilaris*** (canakinumab) is a fully human monoclonal antibody that blocks action of the inflammatory protein interleukin-1 $\beta$  (IL-1 $\beta$ ). *Ilaris* was approved in 2009 in the US, EU and some other markets to treat children four years and older and adults with cryopyrin associated periodic syndrome (CAPS), a group of rare lifelong auto-inflammatory disorders characterized by chronic recurrent fever, urticaria, occasional arthritis, deafness, and potentially life-threatening amyloidosis. Clinical trials are ongoing in other diseases in which IL-1 $\beta$  is believed to play an important role, including gouty arthritis, chronic obstructive pulmonary disease (COPD), type 2 diabetes and systemic juvenile idiopathic arthritis (SJIA).

A treatment for rare lifelong auto-inflammatory disorders

***Lucentis*** (ranibizumab) is the first approved treatment for “wet” age-related macular degeneration (AMD) that is shown to improve vision and vision-related quality of life. AMD is the leading cause of blindness in people over age 50. *Lucentis* is a recombinant humanized high affinity antibody fragment that binds to vascular endothelial growth factors (VEGF), a protein that plays a role in angiogenesis (formation of new blood vessels). *Lucentis* was approved in the US in June 2006 and in the EU in January 2007, and is now approved in more than 75 countries. It was submitted in December 2009 for European regulatory approval for the treatment of visual

First approved treatment for “wet” age-related macular degeneration shown to improve vision

---

impairment due to diabetic macular edema (DME), an eye condition related to long-standing diabetes that may lead to blindness. *Lucentis* is also in development for the treatment of macular edema secondary to retinal vein occlusion (RVO). *Lucentis* is developed in collaboration with Genentech, Inc., which holds the rights to market the product in the US.

***Neoral*** (cyclosporine) is an immunosuppressant to prevent organ rejection following a kidney, liver, heart or lung transplant. *Neoral* is one of the world's most widely used primary immunosuppressants, largely replacing its predecessor *Sandimmun/Sandimmune*, which revolutionized organ transplantation when it was introduced by Novartis in 1982. First launched in 1995, *Neoral* is marketed in approximately 100 countries and is also used in treating select autoimmune disorders such as psoriasis, rheumatoid arthritis, atopic dermatitis and nephrotic syndrome. This product is subject to generic competition.

One of the world's most commonly used primary immunosuppressants

***Reclast/Aclasta*** (zoledronic acid 5 mg) is the first and only once-yearly bisphosphonate infusion for the treatment of different forms of osteoporosis. Sold as *Reclast* in the US and *Aclasta* in the rest of the world, the product is available in 90 countries including the US, EU and Canada. It is the only osteoporosis treatment approved to reduce the incidence of fractures at all three key fracture sites (hip, spine and non-spine) in the treatment of postmenopausal osteoporosis. It is also approved in more than 89 countries for the treatment of Paget's disease of the bone for men and women. The *Reclast/Aclasta* label was expanded in the EU and US to include the reduction in the incidence of clinical fractures after a low trauma hip fracture. The EU has also approved *Aclasta* for the treatment of osteoporosis in men and for the treatment of osteoporosis associated with long-term systemic glucocorticoid therapy in postmenopausal women and in men at increased risk of fracture. *Reclast* is also approved in the US as a treatment to increase bone mass in men with osteoporosis, the prevention and treatment of glucocorticoid-induced osteoporosis in men and women as well as for the prevention of osteoporosis in postmenopausal women. Zoledronic acid, the active ingredient in *Reclast/Aclasta*, is also available under the trade name *Zometa* for use in oncology indications.

First once-yearly infusion for the treatment of different forms of osteoporosis

***Sandostatin SC/Sandostatin LAR*** (octreotide acetate/octreotide acetate for injectable suspension) is indicated for the treatment of patients with acromegaly, a chronic disease caused by over-secretion of pituitary growth hormone in adults. *Sandostatin* is also

Treatment for patients with acromegaly

---

indicated for the treatment of certain symptoms associated with carcinoid tumors and other types of gastrointestinal neuro-endocrine and pancreatic tumors. Clinical trial data published in 2009 demonstrated a significant delay in tumor progression in patients with metastatic neuroendocrine tumors of the midgut who were treated with *Sandostatin LAR*. *Sandostatin* is approved in more than 85 countries. *Sandostatin SC* faces worldwide generic competition. However, patent protection for *Sandostatin LAR* continues in major markets.

***Tasigna*** (nilotinib) first gained regulatory approval in 2007 and is now approved in more than 80 countries, including the US, EU, Switzerland and Japan, to treat a form of chronic myeloid leukemia (CML) in chronic and/or accelerated phase patients resistant or intolerant to existing treatment, including *Gleevec/Glivec*. *Tasigna* was submitted for US and EU regulatory approval for first-line use in CML based on results from the global, randomized Phase III trial Evaluating Nilotinib Efficacy and Safety in Clinical Trials of Newly Diagnosed Ph+ CML Patients (ENESTnd). This was the largest head-to-head comparison of an oral therapy against *Gleevec/Glivec* ever conducted and shows that *Tasigna* produces faster and deeper responses than *Gleevec/Glivec* in adult patients with newly diagnosed Ph+ CML. Novartis is continuing to investigate the potential of *Tasigna* for patients with gastrointestinal stromal tumors (GIST).

Therapy for patients with Philadelphia chromosome-positive chronic myeloid leukemia who are resistant/intolerant to *Gleevec/Glivec* treatment

***Tekturna/Rasilez*** (aliskiren), the latest innovative medicine to treat high blood pressure, has been growing consistently since its launch in 2007 based on positive clinical data demonstrating its prolonged efficacy in lowering blood pressure for more than 24 hours and superiority in clinical trials over ramipril, a leading ACE inhibitor. Novartis is developing various *Tekturna/Rasilez* single-pill combination products. The first, *Tekturna/Rasilez* with hydrochlorothiazide – called *Tekturna HCT* – was approved in the US in January 2008 and in the EU in January 2009, where it is known as *Rasilez HCT*. Another single-pill product, *Tekturna/Rasilez* with valsartan – called *Valturna* in the US (and to be called *Rasival* in the EU) – has been approved by the US FDA and was launched in October 2009. Other single-pill combinations in Phase III development are *Tekturna/Rasilez* with the calcium channel blocker amlodipine and a triple combination therapy with *Tekturna/Rasilez*, amlodipine and a diuretic. In addition, the ASPIRE HIGHER clinical trial program, the largest ongoing cardio-renal outcomes program worldwide, aims to involve more than 35 000 patients in 14 trials, including four mortality and morbidity studies – ALTITUDE, ATMOSPHERE, ASTRONAUT and APOLLO.

Latest innovative medicine to treat high blood pressure patients

---

**Trileptal** (oxcarbazepine) is an anti-epileptic drug for the treatment of partial seizures as adjunctive or monotherapy in adults and children aged four years and above. In the US, *Trileptal* is approved for the treatment of epilepsy. First approved in 1990, *Trileptal* acts by stabilizing neuronal functions, thereby controlling and limiting the spread of seizures. *Trileptal* is approved in more than 100 countries but is subject to generic competition.

Anti-epileptic drug for treatment of partial seizures

**Voltaren/Cataflam** (diclofenac sodium/potassium/Resinate/Free Acid) is a leading non-steroidal anti-inflammatory drug (NSAID) for the relief of symptoms in rheumatic diseases such as rheumatoid arthritis and osteoarthritis and for various other inflammatory or pain conditions. This product, which is subject to generic competition, is available in more than 140 countries in a wide variety of dosage forms, including tablets, drops, suppositories, ampoules and topical therapy. In various markets, low-dose oral forms and the topical therapy of *Voltaren* are available as over-the-counter (OTC) products.

Leading non-steroidal anti-inflammatory drug (NSAID)

**Xolair** (omalizumab) is the first humanized monoclonal antibody approved for the treatment of moderate to severe allergic asthma in the US in adolescents (aged 12 and above) and adults. It is approved for severe allergic asthma in the EU in children (aged six and above), adolescents and adults. *Xolair* is approved in 81 countries, including the US and EU. *Xolair* is being jointly developed with Genentech, Inc., and is co-promoted in the US by Novartis and Genentech.

First humanized monoclonal antibody for treatment of allergic asthma

**Zometa** (zoledronic acid for injection/zoledronic acid 4 mg) is a leading treatment to reduce or delay skeletal-related events from bone metastases (cancer that has spread to the bones). First approved in the US in 2001, *Zometa*, a third-generation bisphosphonate, is available in more than 88 countries. *Zometa* is approved for the treatment of patients with multiple myeloma and patients with documented bone metastasis from solid tumors, including prostate, breast and lung tumors. *Zometa* is also approved in most key markets for the treatment of hypercalcemia of malignancy (tumor-induced excessive levels of calcium). Zoledronic acid, the active ingredient in *Zometa*, is also available under the brand name *Reclast/Aclasta* for use in other non-oncology indications. *Zometa* and *Reclast/Aclasta* may face significant competition in 2010.

Treatment for certain cancers that have spread to bones

---

## Selected compounds in development/pipeline products

**ABF656** (albinterferon alfa-2b), a treatment for chronic hepatitis C, was submitted for regulatory approval in the fourth quarter of 2009 as *Zalbin* in the US and as *Joulferon* in the EU. In Phase III studies, ABF656 (dosed every two weeks) showed similar efficacy to peginterferon alfa-2a (dosed weekly), a current standard of care, but required half the number of injections. ABF656 is being developed and will be marketed in partnership with Human Genome Sciences.

A treatment for chronic hepatitis C

**AIN457** is a monoclonal antibody which targets interleukin-17A, a major trigger of inflammation in a number of serious diseases including uveitis, psoriasis and rheumatoid arthritis. The compound is expected to be filed in 2010 for Behcet's uveitis, and Phase III studies are planned in active and quiescent non-infectious uveitis. AIN457 is also in Phase II trials for psoriasis and rheumatoid arthritis, where initial studies suggested that AIN457 delivered a rapid and sustained response and may represent a new mechanism of action for the treatment of immune-mediated diseases.

A monoclonal antibody which targets a major trigger of inflammation in a number of serious diseases

**ASA404** is a potentially first-in-class tumor-vascular disrupting agent being developed for non-small cell lung cancer (NSCLC). Two Phase III trials are evaluating ASA404 in combination with standard chemotherapy as a treatment for locally advanced or metastatic NSCLC of squamous or non-squamous histology. The ATTRACT-1 Phase III trial investigating ASA404 as first-line therapy completed enrollment in the third quarter of 2009. The ATTRACT-2 Phase III trial investigating ASA404 as second-line therapy is currently enrolling patients. Pending trial outcomes, regulatory submission for use in NSCLC is expected in 2011. ASA404 is also being investigated in combination with taxanes as a first-line treatment of HER2-negative metastatic breast cancer. A Phase IB/II clinical trial is set to start in 2010. ASA404 was licensed from Antisoma, UK in April 2007.

A unique tumor vascular disrupting agent for the treatment of solid tumors

**EPO906** (patupilone) is in Phase III development in platinum resistant/refractory ovarian cancer. With 829 patients enrolled, this is the largest clinical trial ever conducted in this difficult-to-treat patient population. Final results are expected in the first half of 2010 with filing planned for the second half of 2010 assuming that data are positive.

Novel microtubule stabilizer that has shown broad anti-cancer activity

**FTY720** (fingolimod), a sphingosine 1-phosphate receptor modulator, is in registration as an oral disease-modifying treatment for patients with multiple sclerosis, a disabling neurological

An oral disease-modifying treatment for patients with multiple sclerosis

---

condition estimated to affect up to 2.5 million people worldwide. Two Phase III studies examining two doses of FTY720 (0.5 mg and 1.25 mg) in relapsing-remitting multiple sclerosis have been completed. Results from the Phase III TRANSFORMS study showed superior relapse-related efficacy at one year compared to interferon beta-1a given by intra-muscular (IM) injection, a current standard of care. Results from the Phase III FREEDOMS study showed that FTY720 significantly reduced relapse rates and disability progression at two years compared to placebo. The trial showed no significant difference in efficacy between the two doses of FTY720. FTY720 was generally well tolerated with a lower incidence of certain adverse events at the 0.5 mg dose than the 1.25 mg dose. Phase III efficacy and safety data provided a positive benefit-risk profile for the 0.5 mg dose. The regulatory submissions in the US and EU were completed at the end of 2009. FTY720 is licensed from Mitsubishi Tanabe Pharma Corporation.

**INC424** is a Janus kinase (JAK) inhibitor. This oral targeted therapy is now in Phase III clinical trials for the treatment of myelofibrosis, a life-threatening neoplastic condition with no effective medical treatment that is characterized by varying degrees of bone marrow failure, splenomegaly (enlarged spleen) and debilitating symptoms. INC424 has the potential to become a first-in-class therapeutic agent for the treatment of this and other hematologic diseases. Long-term data for INC424 demonstrated durable clinical, functional and symptomatic responses with acceptable hematological safety in patients with myelofibrosis. Other data recently presented show clinical activity in advanced polycythemia vera essential thrombocythemia refractory to hydroxyurea. Novartis licensed the rights to develop and market this compound outside of the US from Incyte Corporation.

A Janus kinase inhibitor for treatment of myelofibrosis and other hematological diseases

**LCZ696** is a dual-acting compound that inhibits the neprilysin (NEP) enzyme and blocks the angiotensin receptor. It entered Phase III trials (PARADIGM-HF outcome study) in December 2009 for the treatment of heart failure, an indication in which ACE inhibitors are the current standard of care. A Phase II pivotal study demonstrated that LCZ696 provides superior blood pressure lowering as compared to valsartan. LCZ696 was well tolerated.

Dual-acting compound that inhibits the neprilysin (NEP) enzyme and blocks the angiotensin receptor

**PRT128** (elinogrel) is a P2Y<sub>12</sub> inhibitor which is direct acting and reversible, and is available in intravenous (IV) and oral routes of administration. The compound is set to enter Phase III development in late 2010 for acute coronary syndrome and chronic coronary heart disease (secondary prevention of atherothrombosis).

A novel P2Y<sub>12</sub> inhibitor for acute coronary syndrome and chronic coronary heart disease

---

Currently, PRT128 is in Phase II and results from this trial are expected in the second quarter of 2010.

**PTK796** is a broad-spectrum aminomethylcycline antibiotic, derived from tetracycline, recently in-licensed from Paratek Pharmaceuticals Inc. The compound has shown broad-spectrum in vitro activity against a wide range of bacteria, including both Gram-positive and Gram-negative strains and highly resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA) and multi-drug resistant *Streptococcus pneumoniae*. PTK796 is currently in Phase III development as an intravenous infusion and oral tablet to treat complicated skin and skin structure infections. Clinical trials are planned in a number of other potential indications, including community-acquired bacterial pneumonia (CABP). Novartis has exclusive worldwide rights to market PTK796.

A broad-spectrum antibiotic to treat a wide range of bacteria

**QAB149** (indacaterol) is a once-daily long-acting beta-2 agonist that offers sustained 24-hour bronchodilation with fast onset of action for the treatment of chronic obstructive pulmonary disease (COPD), a progressive respiratory disease. QAB149 gained EU regulatory approval in November 2009 as *Onbrez Breezhaler*. *Onbrez Breezhaler* has demonstrated greater improvements in lung function, breathlessness and quality of life compared to current therapies and is the first new inhaled compound in Europe for the treatment of COPD in more than seven years. The US FDA has requested additional information on the dosing proposed for QAB149. Novartis is working with the US FDA to determine what further clinical trials will be required.

A treatment for patients with chronic obstructive pulmonary disease (COPD)

**SOM230** is a somatostatin analogue in development for Cushing's disease, acromegaly and carcinoid syndrome that is refractory/resistant to *Sandostatin*. Data from Phase II studies show significant hormone reductions in Cushing's disease and acromegaly patients, and achievement of partial or complete symptom control in patients with refractory/resistant carcinoid syndrome. Based on results from a pivotal trial in Cushing's disease, regulatory submission is planned for 2010. A Phase III trial for acromegaly recently reached its patient accrual target, while a Phase III trial in patients with carcinoid tumors is also ongoing.

Somatostatin analogue in development for Cushing's disease and acromegaly

**TOBI-TIP** (Tobramycin Inhalation Powder; proposed tradename TOBI Podhaler) was submitted for EU regulatory approval in December 2009. TIP is a novel porous-sphere formulation allowing delivery of the appropriate dose of tobramycin with a light and

A treatment for cystic fibrosis

---

portable inhaler device. The proposed indication for TIP in the EU is the long-term management of chronic *Pseudomonas aeruginosa* (Pa) lung infection in patients with cystic fibrosis aged six years and older. As shown in our clinical program, TIP significantly reduces the treatment burden in cystic fibrosis by shortening the administration time by about 75% and eliminating the need for a nebuliser. In Phase III studies, TIP yielded significant improvements over placebo in lung function (FEV1), and was comparable to nebulised tobramycin.

#### **Disclaimer**

These materials contain certain forward-looking statements relating to the Group's business, which can be identified by terminology such as "planned," "expected", "will", "potential", "pipeline", "outlook," or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products, or potential future sales or earnings of the Novartis Group or any of its divisions or business units; or regarding the potential acquisition and merger with Alcon; or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Group regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any new products will be approved for sale in any market, or that any new indications will be approved for existing products in any market, or that such products will achieve any particular revenue levels. Nor can there be any guarantee that the Novartis Group, or any of its divisions or business units, will achieve any particular financial results. Neither can there be any guarantee that the proposed acquisition and merger with Alcon will be completed in the expected form or within the expected time frame or at all. Nor can there be any guarantee that Novartis will be able to realize any of the potential synergies, strategic benefits or opportunities as a result of the proposed acquisition. In particular, management's expectations could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays or government regulation generally; the Group's ability to obtain or maintain patent or other proprietary intellectual property protection; uncertainties regarding actual or potential legal proceedings, including, among others, product liability litigation, litigation regarding sales and marketing practices, government investigations and intellectual property disputes; competition in general; government, industry, and general public pricing and other political pressures; uncertainties regarding the after-effects of the recent global financial and economic crisis; uncertainties regarding future global exchange rates and uncertainties regarding future demand for our products; uncertainties involved in the development of new pharmaceutical products; the impact that the foregoing factors could have on the values attributed to the Group's assets and liabilities as recorded in the Group's consolidated balance sheet; and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing the information in these materials as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

*All product names appearing in italics are trademarks licensed to or owned by Novartis Group companies.*