
Pharmaceuticals

Our Pharmaceuticals Division is a world leader in offering innovation-driven, patent-protected medicines to patients and physicians.

World leader in patent-protected medicines

The Pharmaceuticals Division researches, develops, manufactures, distributes and sells branded pharmaceuticals in the following therapeutic areas:

- Cardiovascular and Metabolism
- Oncology (including Hematology)
- Molecular Diagnostics
- Neuroscience and Ophthalmics
- Respiratory
- Integrated Hospital Care
- Other

The Pharmaceuticals Division is organized into global business franchises responsible for the marketing of various products as well as a business unit called Novartis Oncology responsible for the global development and marketing of oncology products. The Pharmaceuticals Division is the largest contributor among the four divisions of Novartis and reported consolidated net sales of USD 30.6 billion in 2010, which represented 60% of the Group's net sales.

Net sales of USD 30.6 billion in 2010

The division is made up of approximately 80 affiliated companies, which together employed 58 424 full-time equivalent associates as of December 31, 2010, and sells products in approximately 140 countries. The product portfolio of the Pharmaceuticals Division includes more than 60 key marketed products, many of which are leaders in their respective therapeutic areas. In addition, the division's portfolio of development projects includes 147 potential new products, and new indications or new formulations for existing products in various stages of clinical development.

60 key marketed products and 147 potential new products

Selected leading products

Afinitor (everolimus) is an oral inhibitor of the mTOR pathway. It was launched in the US and the EU in 2009 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 (in the US) or after failure of treatment with VEGF-targeted therapy (in the EU). Japanese approval was received in 2010. In October 2010, *Afinitor* received accelerated approval in the US for patients with subependymal giant cell astrocytomas (SEGA) associated with tuberous sclerosis (TS) who require therapeutic intervention, but are not candidates for curative surgical resection. Everolimus is under review in the EU for indications in SEGA under the trade name *Votubia*. *Afinitor* is also in development or being studied in other potential oncology indications. Everolimus, the active ingredient in *Afinitor*, is also available under the trade names *Zortress/Certican* for use in transplantation, and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Afinitor

Comtan and **Stalevo** (entacapone and carbidopa, levodopa and entacapone) are indicated for the treatment of Parkinson's disease. *Stalevo* (carbidopa, levodopa and entacapone) is indicated for 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 from Novartis in more than 50 countries. *Comtan* (entacapone) is also indicated for the treatment of Parkinson's disease patients who experience end-of-dose wearing off and is marketed in approximately 50 countries under a licensing agreement with the Orion Corporation. *Stalevo* and *Comtan* were developed and are manufactured by Orion, and are marketed by Novartis and Orion in their respective territories.

Comtan and Stalevo

Diovan (valsartan), together with **Diovan HCT/Co-Diovan** (valsartan and hydrochlorothiazide), is the world's number one selling branded high blood pressure medication (IMS October 2010). *Diovan* is the only agent in its class approved to treat all of the following: high blood pressure (including in children six to 16 years), high-risk heart attack survivors and patients with heart failure. First launched in 1996, *Diovan* is available in more

Diovan and Diovan HCT/Co-Diovan

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 over 100 countries worldwide. In July 2008, the FDA approved *Diovan HCT* for the first-line treatment of hypertension in patients unlikely to achieve blood pressure control on a single agent. In 2009, *Co-Diovan* was approved for treatment of high blood pressure in Japan. In September 2010, all 27 European Union (EU) member states locally approved *Diovan* for use in children aged six to 18 years. We expect that *Diovan* will face generic challenges in 2011 when the patent on its active ingredient, valsartan, expires in the major countries of the EU, with patent expirations in the US and Japan to follow in 2012 and 2013 respectively

Exelon (rivastigmine tartrate) and **Exelon Patch** (rivastigmine transdermal system): *Exelon* capsules have been available since 1997 to treat mild to moderate Alzheimer's disease (AD) in more than 70 countries. In 2006, *Exelon* became the only cholinesterase inhibitor to be approved for mild to moderate Parkinson's disease dementia in addition to AD in both the US and EU. *Exelon Patch* was approved in 2007 in the US and EU and has been launched in more than 60 countries. The once-daily *Exelon Patch* has shown comparable efficacy to the highest recommended doses of *Exelon* capsules, with significant improvement in cognition and overall functioning compared to placebo. *Exelon* capsules are now subject to generic competition in several markets, including the US.

Exelon and Exelon Patch

Exforge (valsartan and amlodipine besylate) is a single-pill combination of the angiotensin receptor blocker *Diovan* and the calcium channel blocker amlodipine besylate. First approved for the treatment of high blood pressure in Switzerland in 2006, and in the US and EU in 2007, it is now available in more than 80 countries. In 2008, the FDA approved *Exforge* for the first-line treatment of hypertension in patients likely to need multiple drugs to achieve their blood pressure goals. In January 2010, *Exforge* was approved in Japan and also launched in China. *Exforge HCT* (valsartan, amlodipine besylate and hydrochlorothiazide) is a single pill combining three widely prescribed high blood pressure treatments: ARB (valsartan), CCB (amlodipine besylate) and HCT (hydrochlorothiazide).

Exforge

Exforge HCT was approved in the EU and the US in 2009, and is now available in more than 20 countries.

Exjade (deferasirox) is an oral iron chelator approved for the treatment of chronic iron overload due to blood transfusions in patients over two years of age who have a wide range of underlying anemias. Patients with congenital and acquired chronic anemia, such as thalassemia, sickle cell disease and myelodysplastic syndromes require transfusions, which puts them at risk of iron overload. *Exjade* was first approved in 2005 and is now approved in more than 100 countries including the US, EU and Japan. In June 2010, *Exjade* received regulatory approval in China.

Exjade

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 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. Bayer Schering supplies the product to Novartis under an agreement reached in 2007. *Extavia* was approved in the EU in 2008 and since 2009 has been launched in more than 20 markets, including the US.

Extavia

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 in January 2010. *Fanapt* belongs to the class of medication for schizophrenia known as atypical antipsychotics.

Fanapt

Femara (letrozole) is a once-daily oral aromatase inhibitor for the treatment of early stage or advanced breast cancer in postmenopausal women. *Femara* was first launched in 1996 and is currently available in more than 90 countries. *Femara* is approved in the US, EU and other countries in the adjuvant, extended adjuvant and neoadjuvant settings for early stage breast cancer. *Femara* is also approved in the US and other countries as adjuvant therapy for locally advanced breast cancer and for advanced breast cancer following antigen estrogen therapy. *Femara* is approved as neoadjuvant (preoperative) therapy for early stage breast cancer in a limited number of countries. In Japan, *Femara* is approved for the treatment of all

Femara

hormone receptor-positive breast cancer in postmenopausal women. In 2010, the US and EU prescribing information for *Femara* was updated to reflect the results of the BIG 1-98 clinical trial. We expect that *Femara* will face generic challenges in 2011 when the patent on its active ingredient, letrozole, expires in the US and major countries in Europe.

Galvus (vildagliptin), an oral treatment for type 2 diabetes, and **Eucreas**, a single-pill combination of vildagliptin and metformin, have shown promising results during the rollout in Europe following approvals in 2007. *Galvus* is currently approved in 75 countries and launched in 43 countries. The product was approved in Japan in January 2010 under the tradename *Equa*. *Eucreas* was the first single pill combining a DPP-4 inhibitor and another medication to be launched in Europe. *Eucreas* is currently approved in 57 countries and launched in 32 countries, including the EU, as well as Latin America and Asia.

Galvus and Eucreas

Gilenya (fingolimod) is the first in a new class of multiple sclerosis (MS) therapy called sphingosine 1-phosphate receptor modulators. *Gilenya* is the first approved oral disease-modifying treatment for MS in the US, a major advance for people with relapsing MS, the most common form of the disease. *Gilenya* showed superior efficacy by reducing relapses by 52% at one year ($p < .001$) compared to interferon beta-1a IM, a current standard of care. A two-year, placebo-controlled study showed that *Gilenya* significantly reduced the risk of disability progression. *Gilenya* has a well-studied safety and tolerability profile with over 2 600 MS clinical trial patients included in the FDA regulatory review, with some patients in their seventh year of treatment. *Gilenya* was approved as a first-line treatment for relapsing or relapsing-remitting multiple sclerosis (RRMS) in the US, Australia, Switzerland, Russia and the United Arab Emirates. In January 2011, *Gilenya* received a positive opinion from the EU's CHMP as a disease-modifying therapy in patients with highly active RRMS despite treatment with beta interferon, or in patients with rapidly evolving severe RRMS. *Gilenya* is currently under regulatory review with health authorities worldwide, including Canada, Turkey and Brazil. *Gilenya* is licensed from Mitsubishi Tanabe Pharma Corporation.

Gilenya

Gleevec/Glivec (imatinib mesylate tablets/imatinib) is a signal transduction inhibitor approved to treat patients with certain forms of chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST). First launched in 2001, *Gleevec/Glivec* is available in more than 110 countries. *Gleevec/Glivec* is indicated for the treatment of newly diagnosed adult and pediatric patients with a form of CML. *Gleevec/Glivec* is also 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* has received approvals as a post-surgery (adjuvant setting) therapy for GIST in more than 57 countries, including the US and EU.

Gleevec/Glivec

Ilaris (canakinumab) is a fully human monoclonal antibody that selectively binds and neutralizes interleukin-1 β (IL-1 β), a pro-inflammatory cytokine. Since 2009, *Ilaris* has been approved in over 40 countries for the treatment of children aged four years and older and adults suffering from cryopyrin-associated periodic syndrome (CAPS), a group of rare disorders characterized by chronic recurrent fever, urticaria, occasional arthritis, deafness, and potentially life-threatening amyloidosis.

Ilaris

Lescol/Lescol XL (fluvastatin sodium) are lipid-lowering drugs used to reduce cholesterol. *Lescol/Lescol XL* are indicated as an adjunct to diet for the treatment of hypercholesterolemia and mixed dyslipidemia in adults, and to reduce cholesterol in children over nine years and adolescents with heterozygous familial hypercholesterolemia. In addition, for patients with coronary artery disease, *Lescol/Lescol XL* are indicated for secondary prevention of major adverse cardiac events and to slow the progression of coronary atherosclerosis. *Lescol* was first launched in 1994 and *Lescol XL* in 2000. Both are available in more than 90 countries.

Lescol/Lescol XL

Lucentis (ranibizumab) is a recombinant humanized high affinity antibody fragment that binds to vascular endothelial growth factors. *Lucentis* is the first approved drug for wet age-related macular degeneration that has been shown to improve

Lucentis

vision and vision-related quality of life. *Lucentis* was approved in the EU in 2007. It is now approved in more than 85 countries. In January 2011, the European Commission granted Novartis a new indication for *Lucentis* for the treatment of visual impairment due to diabetic macular edema, and since August 2010 it has been filed for this same indication elsewhere around the world, outside of the US. In October 2010, Novartis also filed an application to treat people within the EU with *Lucentis* for visual impairment due to macular edema secondary to retinal vein occlusion. *Lucentis* is developed in collaboration with Genentech, which holds the rights to market the product in the US.

Myfortic (enteric-coated formulation of mycophenolate sodium) is approved in more than 90 countries for the prevention of acute rejection of kidney allografts, and is indicated in combination with cyclosporine and corticosteroids. *Myfortic* was first approved in the US in 2004 and in the EU in 2003.

Myfortic

Neoral (cyclosporine, USP Modified) is an immunosuppressant to prevent organ rejection following a kidney, liver, heart or lung transplant. This microemulsion formulation of cyclosporine is also indicated for treating selected autoimmune disorders such as psoriasis and rheumatoid arthritis. First launched in 1995, *Neoral* is marketed in approximately 100 countries. This product is subject to generic competition.

Neoral

Onbrez Breezhaler (QAB149, indacaterol) is a once-daily beta-2agonist delivered in a single-dose dry-powder inhaler that offers sustained 24-hour bronchodilation with a fast onset of action for the treatment of chronic obstructive pulmonary disease (COPD). Results from a blinded Phase III head-to-head study (INTENSITY) comparing once-daily *Onbrez Breezhaler* with tiotropium, an established therapy for COPD, showed that *Onbrez Breezhaler* is as effective as tiotropium in improving lung function in patients with COPD, while providing greater clinical benefits in terms of reduced breathlessness, lower use of rescue medication, and improved overall health status. While the trial met its primary endpoint and these secondary endpoints relating to key patient outcomes, it did not meet the secondary endpoint of superiority to tiotropium in terms of lung function. *Onbrez Breezhaler* was approved in the EU in December 2009 for two dose strengths, 150 mcg and 300 mcg, for maintenance

Onbrez Breezhaler

bronchodilator treatment in adult COPD patients. Seventeen regulatory approvals have been granted and are valid in over 40 countries, including the EU, Switzerland, and parts of South East Asia and Latin America.

Reclast/Aclasta (zoledronic acid 5 mg) is the first and only once-yearly bisphosphonate infusion for the treatment of different forms of osteoporosis, and for the treatment of Paget's disease of the bone in men and women. Sold as *Reclast* in the US and *Aclasta* in the rest of the world, the product is approved in more than 90 countries including the US, EU and Canada, and is the only bisphosphonate approved to reduce the incidence of fractures at all three key fracture sites (hip, spine and non-spine) in the treatment of postmenopausal osteoporosis. 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 at increased risk of fracture 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 approved in a number of countries in a different dosage under the trade name *Zometa* for certain oncology indications.

Reclast/Aclasta

Ritalin, Ritalin LA, Focalin and **Focalin XR** (methylphenidate HCl, methylphenidate HCl extended release, dexamethylphenidate HCl and dexamethylphenidate HCl extended release) are indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and *Focalin XR* is additionally indicated for adults. *Ritalin* and *Ritalin LA* are also indicated for pediatric and adult narcolepsy. *Ritalin* was first marketed during the 1950s and is available in over 50 countries. *Ritalin LA* is available in over 20 countries. *Focalin* comprises the active d-isomer of methylphenidate and therefore requires half the dose of *Ritalin*.

Ritalin, Ritalin LA, Focalin and Focalin XR

Focalin XR is now approved in Switzerland. *Focalin* and *Focalin XR* are available in the US. Immediate-release *Focalin* is subject to generic competition.

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 the pituitary growth hormone in adults. *Sandostatin* is also indicated for the treatment of patients with certain symptoms associated with carcinoid tumors and other types of gastrointestinal and neuroendocrine pancreatic tumors. *Sandostatin* was first launched in 1988 and is approved in more than 85 countries. *Sandostatin SC* faces worldwide generic competition. Formulation patents covering *Sandostatin LAR* expired in July 2010 in all countries except the US, where the expiration of formulation patents begins at the end of 2014. The expiration of the last formulation patent in the US will be in January 2017. There are currently no generic versions of *Sandostatin LAR* approved in major markets.

Sandostatin SC/Sandostatin LAR

Tasigna (nilotinib) is a signal transduction inhibitor of the tyrosine kinase activity of BCR-ABL, Kit and the PDGF-receptor. Since 2007, *Tasigna* has gained regulatory approval in more than 85 countries including the US, the EU, Switzerland and Japan, to treat patients with a form of chronic myeloid leukemia (CML) in chronic and/or accelerated phase patients resistant or intolerant to existing treatment including *Gleevec/Glivec*. Results from the global, randomized Phase III trial called ENESTnd (Evaluating Nilotinib Efficacy and Safety in Clinical Trials of Newly Diagnosed Ph+ CML Patients), a head-to-head comparison against *Glivec*, show that *Tasigna* produced faster and deeper responses than *Glivec* in adult patients with newly-diagnosed Ph+ CML. The ENESTnd 24-month follow-up presented at the American Society of Hematology (ASH) confirmed that *Tasigna* continued to surpass *Glivec* in inducing deeper and more durable cytogenetic and molecular response and showed a lower incidence in transformation to accelerated phase and blast crisis. Based on the 12-month ENESTnd data, applications were submitted to health authorities worldwide for first-line CML. *Tasigna* is now approved in the US, EU, Japan, Switzerland and other countries for the treatment of adult

Tasigna

patients with a form of newly diagnosed CML. Trials are also underway examining the use of *Tasigna* in patients with metastatic GIST and with c-Kit mutated, advanced melanoma.

Tekturna/Rasilez (aliskiren) is a treatment for high blood pressure, and the first and only approved direct renin inhibitor. *Tekturna/Rasilez* was approved in the US and EU in 2007, and is now available in more than 80 countries. The product is known as *Tekturna* in the US and *Rasilez* in the rest of the world. There are various *Tekturna/Rasilez* single-pill combination products. The first single-pill combination product, *Tekturna/Rasilez* with hydrochlorothiazide – called *Tekturna HCT* – was approved in the US in 2008 and in the EU in 2009, where it is known as *Rasilez HCT*. Another single-pill combination product, *Tekturna/Rasilez* with valsartan – called *Valturna* in the US (and to be called *Rasival* outside of the US) – has been approved by the FDA and was launched in the US in 2009. In September 2010, we withdrew our application for EU Marketing Authorization for *Rasival*. The application was withdrawn following a CHMP request to provide additional data satisfying the relevant EU guidelines. We were unable to provide the requested data within the timeframe of the review process. The single-pill combination of *Tekturna/Rasilez* with the calcium channel blocker amlodipine besylate, known as *Tekamlo* in the US (and to be called *Rasilamlo* in the EU) was approved by the FDA in August 2010 and was filed with the European Medicines Agency (EMA) in December 2009. The single-pill triple combination of *Tekturna/Rasilez* with amlodipine besylate and hydrochlorothiazide was approved in December 2010 in the US under the product name *Amturnide*. It was filed with the EMA in May 2010.

Tekturna/Rasilez

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 and pain conditions. *Voltaren/Cataflam* was first launched in 1973 and is available in more than 140 countries. This product, which is subject to generic competition, is marketed by the Pharmaceuticals Division in a wide variety of dosage forms, including tablets, drops, suppositories, ampoules and topical therapy. In addition, in various countries, our Consumer Health Division's OTC Business Unit markets low-

Voltaren/Cataflam

dose oral forms and the topical therapy of *Voltaren* as over-the-counter products.

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 more than 80 countries, including the US in 2003 and the EU in 2005. *Xolair* is being jointly developed with Genentech and is co-promoted in the US by Novartis and Genentech.

Xolair

Zometa (zoledronic acid for injection/zoledronic acid 4 mg) is a leading treatment to reduce or delay skeletal-related events (SREs), including pathologic fracture, spinal cord compression, and/or requirement of radiation therapy or surgery to bone, in patients with bone metastases (cancer that has spread to the bones) from solid tumors and multiple myeloma. First approved in the US in 2001 for the treatment of hypercalcemia of malignancy (tumor-induced excessive levels of calcium), *Zometa* is approved in more than 100 countries for this indication as well as for the treatment of patients with multiple myeloma and patients with bone metastasis from solid malignancies, including prostate, breast and lung cancer. Zoledronic acid, the active ingredient in *Zometa*, is also available under the trade names *Reclast/Aclasta* for use in non-oncology indications. *Zometa* and *Reclast/Aclasta* may face significant competition from denosumab, a new Amgen product recently approved for the treatment of postmenopausal osteoporosis, and in the US oncology setting for SRE reduction or delay in patients with advanced malignancy involving bone. Denosumab is not approved in the multiple myeloma setting.

Zometa

Zortress/Certican (everolimus) is an mTOR inhibitor indicated for the treatment of transplant rejection in combination with cyclosporine and corticosteroids. It has been sold as *Zortress* in the US since April 2010 and as *Certican* in the rest of the world since 2003. It is approved in the US for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal transplant, and launched in more than 85 countries for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving

Zortress/Certican

an allogenic renal or cardiac transplant. Everolimus, the active ingredient in *Zortress/Certican*, is also available under the trade name *Afinitor* for the treatment of patients with advanced renal cell carcinoma after failure with certain treatments, and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Key compounds in development (select products in Phases II, III and Registration)

ACZ885 (canakinumab) was filed in the EU in December 2010 for the treatment of acute attack in gouty arthritis and is planned to be filed in the US in early 2011. The Phase III program in gouty arthritis followed a Phase II program that showed superior pain relief and a much reduced risk of flares compared to an injectable corticosteroid. Phase III trials are ongoing for the treatment of systemic onset juvenile idiopathic arthritis. ACZ885 is also being investigated in Phase II for the treatment of type 1 and type 2 diabetes. A Phase III program in secondary prevention of cardiovascular events is also planned to be initiated in 2011.

ACZ885

AEB071 (sotrastaurin) is a low molecular weight, selective inhibitor of protein kinase-C (PKC). Inhibition of PKC reduces T-cell activation through a novel calcineurin-independent pathway. The molecule is in Phase II clinical development for the treatment of autoimmune indications (including psoriasis) and for the prevention of solid organ allograft rejection (kidney and liver transplantation).

AEB071

AFQ056 is a metabotropic glutamate receptor 5 (mGluR5) antagonist in Phase II development for the treatment of Parkinson's disease levodopa-induced dyskinesia. No therapy has previously been approved for this condition, which represents a complication after dopamine-replacement therapy in Parkinson's patients and which is characterized by a variety of hyperkinetic movements. A phase II study in adult patients with Fragile X syndrome was initiated in the fourth quarter of 2010.

AFQ056

AGO178 (agomelatine) is an MT1/MT2 receptor agonist and 5-HT2c antagonist for the treatment of major depressive disorder. It has a novel, synergistic mechanism of action. Three Phase III trials have recently been completed in the US. Data from these trials confirmed the known efficacy and safety profile of the drug. An oral dispersible formulation of AGO178 will now be studied in additional Phase III trials to further explore its risk/benefit and pharmacokinetic profile. Novartis licensed from Servier the exclusive rights to develop and market the compound in the US and several other countries.

AGO178

AIN457 (secukinumab) is a human monoclonal antibody neutralizing interleukin-17A, a key pro-inflammatory cytokine expressed by TH17 cells. The compound is in Phase III development in uveitis and in Phase II development in psoriasis and arthritides (rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis), where initial studies suggested that AIN457 provides a new mechanism of action for the treatment of immune-mediated diseases. The Phase III study examining AIN457 for non-infectious uveitis in patients with Behcet's disease did not meet its primary endpoint and the data do not support submission of AIN457 for this indication.

AIN457

BAF312 is an oral, second-generation sphingosine-1 phosphate receptor modulator in Phase II development for relapsing-remitting multiple sclerosis. BAF312 binds selectively to the sphingosine-1 phosphate receptor subtypes 1 and 5, and has a relatively short half-life.

BAF312

DEB025 (alisporivir) is a cyclophilin inhibitor for the treatment of hepatitis C virus infection (HCV). DEB025 was in-licensed from Debiopharma in early 2010. A Phase IIb study in HCV genotype 1 treatment-naïve patients was completed in 2010 and the results of sustained viral response at 24 weeks were presented to health authorities during the fourth quarter. The FDA and EMA supported a Phase III program for DEB025, which is planned to start in early 2011. In 2010, we also initiated a clinical trial with DEB025 in HCV G1 treatment-experienced patients, and a clinical trial with a novel study design in HCV G2/3 patients where interferon-free/interferon-sparing regimens are being investigated.

DEB025

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. Novartis has licensed the rights to INC424 from Incyte for development and potential commercialization outside the US. Two Phase III clinical trials, COMFORT-1 and COMFORT-2 have been completed. In December, first interpretable results of COMFORT-1 showed the trial met its primary and secondary endpoints. Results from COMFORT-2 are expected in the first half of 2011. Long-term data regarding INC424 was published in September and demonstrated durable clinical, functional and symptomatic responses with acceptable hematological safety in patients with myelofibrosis. In October, the first US patient was dosed in the Phase III RESPONSE trial comparing INC424 with best available treatment in Polycythemia Vera. This trial is managed by Incyte in the US and by Novartis in the rest of the world. First patients outside the US are expected to be dosed in early 2011.

INC424

Joicela (lumiracoxib) is an oral COX-2 inhibitor for osteoarthritis, which Novartis formerly marketed under the brand name *Prexige*. Based on requests from several worldwide health authorities, most marketing authorizations for lumiracoxib were withdrawn due to concerns related to its post-marketing liver safety profile. A specific genetic biomarker has recently been identified which predicts the risk of severe liver injury in patients. In 2009, Novartis submitted a new marketing authorization application in the EU for lumiracoxib (100 mg once daily) under the brand name *Joicela* for symptomatic relief in the treatment of osteoarthritis of the knee and hip in patients who are non-carriers of this genetic biomarker. Similar recommendations related to pre-treatment genetic testing are being implemented wherever the product remains commercially available for osteoarthritis.

Joicela

LBH589 (panobinostat) is a highly potent pan deacetylase inhibitor targeting the epigenetic regulation of multiple oncogenic pathways, with development focused on hematological disease. In Hodgkin's lymphoma, final analysis of a pivotal Phase II study in relapsed/refractory patients was presented at ASH and LBH589 was filed in Hodgkin's lymphoma

LBH589

in the US based on the results from this study. Regulatory submissions in Hodgkin's lymphoma are also planned worldwide. A Phase III trial in patients in complete response after an autologous stem cell transplantation for Hodgkin's lymphoma (PATH) was started in June 2010, while a Phase III trial for multiple myeloma began in December 2009 (PANORAMA-1). We anticipate filing LBH589 in multiple myeloma in 2013.

LCQ908 is a diacylglycerol acyltransferase1 (DGAT1) inhibitor. DGAT1 catalyzes the final committed step in triglyceride synthesis and is believed to play a key role in whole body energy homeostasis. Inhibition of DGAT1 represents a novel approach to treat metabolic disease and LCQ908 is currently in Phase II development for the treatment of diabetes and other metabolic disorders.

LCQ908

LCZ696 is a first-in-class angiotensin receptor neprilysin inhibitor (ARNI), a dual-acting compound that delivers concomitant inhibition of neprilysin (NEPI) and blockage of the angiotensin type 1 (AT1) receptor (ARB). The compound entered Phase III development at the end of 2009 for the treatment of heart failure, an indication in which ACE inhibitors are the current standard of care.

LCZ696

Lucentis (ranibizumab) was approved in the EU in January 2011 for the treatment of visual impairment secondary to diabetic macular edema. A file for the retinal vein occlusion indication was submitted in the EU in October 2010. A Phase III program for the Pathologic myopia indication was initiated with first patient visit in October 2010.

Lucentis

NVA237 (glycopyrronium bromide), a long-acting muscarinic antagonist (LAMA) providing sustained bronchodilation, is being developed as a once-daily treatment for COPD in a single-dose dry-powder inhaler. Phase II trials have concluded successfully, indicating that NVA237 has a comparable efficacy profile compared to tiotropium, the only LAMA presently on the market, with the potential for improved tolerability and a faster onset of action. A Phase III study commenced in 2009 and first submissions are planned in 2011.

NVA237

PKC412 (midostaurin) is an oral, multi-targeted, kinase inhibitor in Phase III development for treatment of patients with acute myeloid leukemia (AML) and in Phase II development for aggressive systemic mastocytosis (ASM). Filing is expected for ASM with Phase II data in 2013 and for an indication in FLT3-mutated AML with Phase III data by 2014.

PKC412

PRT128 (elinogrel), a P2Y12 inhibitor, is a direct-acting, reversible antiplatelet agent that is being developed with both an oral and an intravenous route for administration for the treatment of patients with chronic coronary heart disease and acute coronary syndrome to reduce the risk of recurrent cardiovascular events. The results of the INNOVATE-PCI Phase II study were presented at the European Society of Cardiology congress in August 2010 and PRT128 is expected to enter Phase III development in 2011.

PRT128

PTK796 (omadacycline) is an antibiotic in-licensed from Paratek Pharmaceuticals Inc. The compound is an aminomethylcycline, derived from tetracycline, which is not affected by the common mechanisms of tetracycline resistance and has demonstrated in vitro activity against resistant bacterial pathogens that most commonly cause complicated skin and skin structure infections (*Staphylococcus aureus*) and community acquired pneumonia (*Streptococcus pneumoniae*). The antibiotic is also active against *Haemophilus influenzae*, atypical pathogens (such as *Legionella pneumophila*), and many anaerobes. PTK796 is currently entering Phase III development as an intravenous infusion with oral tablet follow-on to treat complicated skin and skin structure infections. Clinical trials are planned in a number of other potential indications, including community acquired pneumonia, and diabetic foot infections, caused by highly resistant bacteria such as methicillin-resistant *Staphylococcus aureus* and multi-drug resistant *Streptococcus pneumoniae*. Novartis has gained exclusive worldwide rights to market PTK796.

PTK796

QAB149 (indacaterol) has been submitted for regulatory consideration in Japan, China and a number of other countries to treat chronic obstructive pulmonary disease (COPD). In the US, following a Complete Response Letter received from the FDA in October 2009, Novartis has completed additional studies to further characterize the dosing regimen for indacaterol.

QAB149

Incremental benefits have been observed with indacaterol in escalating doses from 75 mcg up to 300 mcg, with higher doses showing increasing benefit for patients, particularly those with more severe cases. Following an FDA request to explore the lower part of the dose response curve, data supporting the 75 mcg and 150 mcg doses were submitted in the US at the end of September 2010. The application for US approval (under the brand name *Arcapta Neohaler*) is due to be reviewed by an FDA Advisory Committee in March 2011.

QMF149 is a once-daily fixed dose combination of the long-acting beta2-agonist QAB149 and the Merck (formerly Schering-Plough) inhaled corticosteroid mometasone delivered in a single-dose dry-powder inhaler. Phase II development for asthma and chronic obstructive pulmonary disease is currently ongoing. Filing in the EU is expected in 2014. Activities directly related to US development will not be initiated.

QMF149

QVA149 is a once-daily fixed dose combination of the long-acting beta2-agonist QAB149 and the long-acting muscarinic antagonist NVA237 (glycopyrronium bromide), which is being investigated for the treatment of chronic obstructive pulmonary disease, in a single-dose dry-powder inhaler. Phase II studies have been successfully completed and results demonstrated that fixed dose combination QVA149 provided superior bronchodilation compared to QAB149 or placebo, which was sustained over 24 hours. The compound had a fast onset of action and was well tolerated with a good safety profile. Phase III development commenced in 2010 and first submission is planned in 2012.

QVA149

QTI571 (*Glivec*, imatinib mesylate tablets/imatinib), an inhibitor of the tyrosine kinase activity, is currently in development for pulmonary arterial hypertension (PAH). PAH is a rare, progressive, proliferative disease with high morbidity and mortality. A Phase III program in severe PAH patients started in 2009 and first regulatory submission is planned for 2011.

QTI571

RAD001 (*Afinitor*, everolimus) is an oral inhibitor of the mTOR pathway. Phase III studies are underway in patients with breast cancer, lymphoma, gastric cancer and tuberous sclerosis (TS). Everolimus is under review in the EU for patients with subependymal giant cell astrocytomas (SEGA) associated with

RAD001

TS, based on 28-patient Phase II data that showed meaningful reduction in SEGA volume. It was approved for this indication in the US in October 2010. Also, a Phase III study to further explore the clinical benefits of everolimus for patients with SEGA associated with TS has completed enrollment. Regulatory submissions have been completed in the US, EU and Japan in advanced neuroendocrine tumors (NET). RADIANT-3 (RAD001 In Advanced Neuroendocrine Tumors), a Phase III study in pancreatic NET met its primary endpoint of progression-free survival (PFS). RADIANT-2 did not meet its primary endpoint of PFS. Results showed that everolimus plus octreotide LAR extended the median time without tumor growth when compared to placebo plus octreotide LAR. In addition, results from a randomized Phase II study showed the addition of everolimus to the hormonal therapy tamoxifen in patients with advanced metastatic breast cancer delayed disease progression compared to tamoxifen alone.

RLX030 is a recombinant form of human relaxin-2. The molecule was obtained upon the acquisition of the US biotech Corthera, Inc. in February 2010. It is being developed for patients hospitalized for acute heart failure. The Phase II data in this population indicated rapid and sustained symptom relief along with an outcome benefit, following a continuous intravenous infusion, on top of standard of care. The ongoing Phase III development program will test the short- and long-term efficacy and safety.

RLX030

SOM230 (pasireotide) is a somatostatin analogue in development for patients with Cushing's disease, acromegaly and refractory/resistant carcinoid syndrome. Data from a pivotal study in Cushing's disease showing significant reduction of cortisol secretions are the basis for regulatory submissions of SOM230 in subcutaneous formulation. Data from a Phase II study suggest reduction of growth hormone in acromegaly patients, and achievement of partial or complete symptom control in patients with refractory/resistant carcinoid syndrome. A Phase III trial comparing SOM230 LAR against *Sandostatin* LAR in patients with acromegaly is anticipated to report results in 2011. In addition, a Phase III trial comparing SOM230 LAR against *Sandostatin* LAR in patients with carcinoid tumors refractory/resistant to somatostatin analogues is also ongoing. Applications have been submitted to the EU and Swiss

SOM230

regulatory authorities for the use of SOM230 in Cushing's disease and a response is expected by the end of 2011.

Tasigna (nilotinib) is to be studied in patients with GIST and melanoma, and a Phase III registration trial evaluating *Tasigna* versus *Glivec* as first-line treatment for unresectable or metastatic GIST is actively recruiting. A separate trial for patients with cKIT mutated melanoma began in April 2010.

Tasigna

TKI258 (dovitinib) is a multi-targeted kinase inhibitor of FGFR, VEGFR and PDGFR. With a unique preclinical profile, its development is focused on FGFR driven diseases. Clinical proof of concept was recently demonstrated in renal cell carcinoma (RCC). A Phase III registration trial in patients with RCC is planned to start in 2011.

TKI258

Xolair (omalizumab): Following approval in the EU for a liquid formulation of Xolair, preparation is ongoing for the launch. Novartis and Genentech have started development of omalizumab in a new indication, Chronic Idiopathic Urticaria, with Phase III studies due to start in 2011.

Xolair

Zometa (zoledronic acid) is a leading treatment to reduce or delay skeletal-related events in patients with bone metastases (cancer that has spread to the bones) from solid tumors and multiple myeloma. In 2008, new clinical trial results (ABCSG-12) showed that *Zometa* reduced the risk of breast cancer returning when used as an adjuvant breast cancer treatment in premenopausal women who received *Zometa* following curative surgery and hormone therapy, including goserelin treatment to suppress ovarian function and induce menopause. Novartis filed these data in the US and EU in December 2009, requesting an update to the *Zometa* prescribing information. In 2010, results of the AZURE trial, to investigate the potential use of *Zometa* as adjuvant therapy in premenopausal and postmenopausal women with early breast cancer, did not meet its primary endpoint in the overall patient population. However, in a predefined subgroup of women with well-established menopause, an improvement in disease-free survival and overall survival was shown in the *Zometa* arm. Regulatory filings in the US and EU for the potential use of *Zometa* for adjuvant breast

Zometa

cancer treatment have been withdrawn, and Novartis will discuss future regulatory plans with health authorities worldwide based on these data.

Zortress/Certican (everolimus) is an mTOR inhibitor with immune/non-immune cell proliferation inhibition being developed for prevention of solid organ transplant rejection. In 2008, Phase III development was initiated worldwide for the prevention of organ rejection in liver transplantation.

Zortress/Certican

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