

Novartis highlights strong R&D pipeline, plans for multiple new product launches and novel projects moving into late-stage trials

- *One of the strongest pipelines with 138 projects in pharmaceutical development, focusing on areas of high unmet medical needs*
- *Exforge¹ and Tekturna¹ (US/EU, hypertension), Galvus¹ (US/EU, diabetes), Tasigna¹ (US/EU, cancer) and Lucentis (EU, eye disease) all submitted for major approvals*
- *Accelerated US and European Union submissions completed for Tasigna and Aclasta/Reclast¹ (osteoporosis) in 2006 ahead of plans for next year*
- *Late-stage compounds moving into pivotal trials – FTY720 (multiple sclerosis), QAB149 (COPD/asthma), AGO178 (depression), ABF656 (hepatitis C), RAD001 (cancer) and SOM230 (Cushing's disease)*
- *Among vaccine portfolio highlights, H5N1 pre-pandemic influenza vaccine shows positive results in Phase II volunteer trial and EU submission completed*

London, November 28, 2006 – Novartis unveiled today new data on its promising pipeline amid plans for multiple new product approvals and launches over the next two years. Many of these anticipated approvals are for potentially best-in-class medicines that would advance treatment standards for patients with hypertension, diabetes, cancer and other diseases.

Novartis highlighted progress throughout its pipeline, particularly the advance of pharmaceutical compounds to pivotal trials before regulatory submission as well as the development portfolio in the newly created Vaccines and Diagnostics division.

The following compounds are moving into pivotal late-stage trials: **FTY720** (fingolimod) for multiple sclerosis, **QAB149** (indacaterol) for COPD and asthma, **AGO178** (agomelatine) for depression and **ABF656** (Albupheron™) for hepatitis C as well as **RAD001** (everolimus) for cancer and **SOM230** (pasireotide) for Cushing's disease.

"I am pleased that our sustained focus on innovation and drive to address unmet medical needs have enabled us to further strengthen our pipeline and file several new drugs for regulatory review over the past 12 months," said Dr. Daniel Vasella, Chairman and CEO of Novartis.

¹ Brand name awaiting approval by regulatory authorities. All product names appearing in italics are trademarks of Novartis Group Companies.

“Over the next two years we will launch several innovative medicines and continue to invest aggressively in discovery research and development activities and complement our own skills and technologies through attractive collaborations,” Dr. Vasella said.

In total, Novartis now has 138 projects in pharmaceutical clinical development. Of these, 94 projects are in confirmatory development (Phase IIb, Phase III or registration with regulatory authorities). A total of 50 are new molecular entities (NMEs), while 88 are life-cycle management projects involving new indications or formulations.² More than 20 projects have been added to the pipeline during 2006. Key R&D areas are cardiovascular/metabolic conditions, oncology and neuroscience as well as respiratory and infectious diseases.

Novartis has completed many submissions in 2006 to regulatory authorities for new compounds as well as new indications for medicines already available to patients.

The US and EU regulatory submissions were accelerated and completed ahead of schedule in 2006 for two compounds: **Tasigna** (nilotinib) as a new treatment option for patients with resistance and/or intolerance to treatment with *Gleevec/Glivec* for certain forms of chronic myeloid leukemia (CML), and also for **Aclasta/Reclast** (zoledronic acid) as a once-yearly bisphosphonate infusion for women with postmenopausal osteoporosis.

US regulatory decisions are also expected for **Tekturna** (aliskiren), a renin inhibitor for hypertension, and **Exforge** (valsartan and amlodipine), a single-tablet combination of the two most prescribed hypertension medicines in their respective classes.

Awaiting European Commission approval are **Exforge** and **Lucentis**, a new treatment option for patients with the “wet” form of age-related macular degeneration (AMD), after both compounds received positive recommendations in November from the Committee for Medicinal Products for Human Use (CHMP). The Commission generally follows the recommendations of the CHMP and delivers a final decision within two to three months.

A US regulatory decision is also expected in the first half of 2007 for **Galvus** (vildagliptin) as a once-daily oral treatment for patients with type 2 diabetes. The US Food and Drug Administration (FDA) extended the review period for *Galvus* by three months from November 2006 after recently available clinical data were submitted to support the proposed dosing and indications as well as complement earlier data on the risk/benefit profile.

Sustained leadership in hypertension

Approvals of *Exforge* and *Tekturna* would further strengthen the leadership of Novartis in offering a broad range of treatments for patients with hypertension, complementing the in-market brands *Diovan* and *Lotrel*.

High blood pressure – and its consequences – is the world's No. 1 killer, estimated by the American Heart Association to affect one in four adults, or around one billion people globally. Despite extensive use of current therapies, about 70% of all people with high blood pressure do not reach target blood pressure levels. Many require two or more medicines to gain control.

Exforge is the first medicine to combine the angiotensin receptor blocker (ARB) valsartan (*Diovan*) and the calcium channel blocker (CCB) amlodipine besylate. More than 80% of *Exforge* patients in studies reached their recommended blood pressure goals and also experienced a lower rate of peripheral edema (swelling of the ankles) compared to those taking amlodipine alone.

² Figures for life-cycle management projects have been adjusted to conform with industry benchmarking figures. However, no change has been made in the definition or method of reporting new molecular entities.

Tekturna, which was developed in collaboration with Speedel, has shown a strong efficacy profile in hypertension patients. New data presented at the event showed *Tekturna* demonstrated a statistically significant ($p=0.0004$) reduction in blood pressure compared to a diuretic (hydrochlorothiazide), while results from this 12-week trial also showed strong efficacy in combination with the same diuretic in obese patients. *Tekturna* has shown placebo-like safety at the proposed maximum once-daily dose of 300 mg.

In another new study, the combination of *Tekturna* and *Diovan* showed a significant additive reduction in blood pressure compared to *Diovan* alone, with a drop in systolic blood pressure of about 17 mm Hg compared to about 13 mm Hg for either *Tekturna* or *Diovan* alone.

Additional data support efficacy and safety of *Galvus*

Novartis is confident in the efficacy and safety of *Galvus* and in obtaining US approval for this once-daily oral treatment for patients with type 2 diabetes. Results from recently completed clinical trials are being submitted to the FDA involving an additional 1,000 patient-years of treatment experience.

These data include results from short- and long-term studies for periods of up to two years, both as a monotherapy or in combination with other anti-diabetes medicines. They further support the proposed dosing regimen and indications as well as complement the risk/benefit profile of *Galvus*. In particular, they provide further evidence confirming data submitted earlier to the FDA showing that skin findings identified in a single species during a preclinical animal study have not been seen in clinical studies with type 2 diabetes patients.

New data presented at the event again confirmed the once-daily efficacy of *Galvus*, while pooled monotherapy data showed a 1.1% reduction in HbA1c (a measure of average blood sugar levels) in initial use by type 2 diabetes patients starting treatment. The results of a 104-week trial continued to show the sustained reduction of 1% in HbA1c seen at 52 weeks, but narrowly missed the primary endpoint of non-inferiority versus metformin. However, *Galvus* was better tolerated than metformin, particularly with a superior gastrointestinal tolerability profile.

Vaccines pipeline supports existing franchises and explores new fields

Novartis has assembled a strong pipeline of investigational human vaccine projects following the acquisition of Chiron in April 2006, focusing on supporting existing franchises in influenza, meningitis and travel vaccines while exploring new disease areas.

Among new data presented at the event were the positive results of a Phase II trial involving 500 volunteers inoculated with an **adjuvanted H5N1 pre-pandemic vaccine**. Results showed that various levels mandated by European regulators for seroprotection, seroconversion increase and mean geometric increase of H5N1-specific antibodies were achieved. Novartis announced today that this vaccine has been submitted for European approval for use as a pre-pandemic vaccine to boost the immune system's ability to defend against infections from an H5N1 strain.

The *OptaFlu* seasonal influenza vaccine, which is based on novel cell culture technology instead of traditional egg-based production, showed in pivotal Phase III data that it was highly capable of producing an immune response ("immunogenic"), at least as strong as the egg-based vaccine Agrippal[®] for each of the three influenza strains studied. It was also well tolerated, showing no meaningful differences in the safety profile compared to traditional egg-based vaccines. The EU submission was completed in 2006, while the US submission is planned for 2008.

Novartis also announced progress in the development of its conjugate quadrivalent *MenACWY* vaccine against the A, C, W135 and Y serogroups of *Neisseria meningitides*, important causes of bacterial meningitis. This devastating disease is estimated to strike about three to five of 100,000 people per year – particularly infants and children. Phase III trials involving 13,000 people started in April 2006, targeting regulatory submission for use in infants, adolescents and adults.

A vaccine for the B serogroup of **meningitis B**, for which there is currently no effective vaccine, is also in Phase II studies to identify dosing in adolescents, with data expected by the end of 2007.

Productive innovation filling the early-stage pipeline

New discovery approaches at the Novartis Institutes for BioMedical Research (NIBR), which was created four years ago to enhance the Group's long tradition of drug discovery, are contributing novel compounds to clinical development.

The number of new molecular entities in the NIBR portfolio has increased to more than 70 in 2006 (compared to 55 in 2004), driven in part by new target discovery, enhanced structural biology, and rapid growth in the number of biological therapeutic drug candidates. These include antibodies, which now constitute about 25% of the NIBR portfolio.

Selected Pipeline Event highlights

Among projects highlighted at the event were the following:

- **Aclasta/Reclast** (zoledronic acid), a once-yearly bisphosphonate treatment for women with postmenopausal osteoporosis, has been submitted for US and EU approval earlier than planned. This was based on pivotal Phase III data showing that patients taking *Aclasta/Reclast* experienced a highly significant 70% risk reduction in new spine fractures ($p < 0.0001$) and a 41% risk reduction in hip fractures ($p = 0.0024$) over three years compared to placebo. This met the study's two primary endpoints. Additionally, all secondary endpoints were met, including risk reduction in clinical spine and non-spine fractures. This high level of efficacy was sustained in the second and third years of the study, while *Aclasta/Reclast* was generally safe and well tolerated.
- **AEB071**, a first-in-class protein kinase C (PKC) inhibitor, is aiming to become the first oral treatment that inhibits T-cell activation since the introduction of calcineurin inhibitors. T-cell activation is an early step in autoimmune diseases such as psoriasis and is also essential for the rejection of transplanted organs. AEB071 blocks a pathway critical to T-cell activation and has shown promise in organ transplantation as well as in autoimmune disorders. It has shown improvements in psoriatic skin lesions in an early proof-of-concept study and recently started Phase II clinical trials for organ transplantation (prevention of graft rejection). Submission is planned for after 2010.
- **AGO178** (agomelatine), seeking to become a new once-daily treatment for patients with major depression, is set to begin Phase III trials in the US by the end of 2006. The US rights to this compound were acquired in March 2006 from Servier. AGO178 has shown efficacy comparable to current standard therapies such as SSRIs (selective serotonin reuptake inhibitors) and SNRIs (serotonin and norepinephrine reuptake inhibitors) while offering improved tolerability, including a low propensity to cause sexual dysfunction and weight gain as well as an improvement in the quality of sleep. US submission is planned for 2008.
- **ABF656 (Albuferon™)** (albumin interferon alpha-2b), a novel long-acting interferon targeting hepatitis C, is entering Phase III trials. Interim results from Phase II trials, in which treatment-naïve patients received Albuferon in combination with ribavirin, showed it has the potential for an improved efficacy and tolerability profile with the need for fewer injections compared to pegylated interferon, the current standard of care. Hepatitis C is a liver disease caused by a chronic viral infection estimated to affect more than 170 million patients worldwide. Novartis and Human Genome Sciences will co-promote Albuferon in the US, while Novartis will have exclusive rights in the rest of the world. The first regulatory submission is planned for 2009.

- **EPO906** (patupilone), a novel tubulin polymerizing compound known as an epothilone, has experienced unexpectedly slow patient accrual for a registration trial in ovarian cancer that was started in 2005, delaying submission. A protocol amendment has been made and the number of centers expanded.
- **Exelon Patch** (rivastigmine transdermal patch) has been submitted for US and EU approval as a once-daily treatment for patients with Alzheimer's disease. The IDEAL study of about 1,200 patients showed that *Exelon Patch* provided benefits across a wide range of symptoms and that the target dose was well tolerated. Transdermal patches are designed to provide controlled, continuous delivery of a medicine through the skin, meaning patients could potentially avoid gastrointestinal problems associated with certain oral medicines. Patients using *Exelon Patch* had improved memory and thinking, and were also better able to perform everyday activities than those on placebo.
- **Exjade** (deferasirox) has been launched in the US and Europe as the first and only once-daily oral iron chelator for chronic iron overload in transfusion-related conditions. It is now being studied in patients with non-transfusional-related iron overload. Phase I/II safety and efficacy studies are enrolling patients, with the first data expected in 2008.
- **FTY720** (fingolimod), seeking to become the first oral disease-modifying treatment for patients with relapsing multiple sclerosis (MS), is being studied in a Phase III program underway with the goal of enrolling more than 3,000 patients worldwide. A two-year placebo-controlled program (FREEDOMS) is measuring reductions in the frequency of relapses and disability progression in MS patients. A one-year trial (TRANSFORMS) started in May 2006 comparing FTY720 with interferon beta-1a (Avonex[®]). Two-year data from the extension of a Phase II trial showed sustained benefits, indicating that FTY720 could provide an important new option for the estimated 2.5 million people worldwide suffering from this disabling neurological disease. Submission remains on track for 2009.
- **LBH589**, a highly potent deacetylase inhibitor shown to impede multiple pathways implicated in cancer, is planned to start a pivotal Phase II registration study by the end of 2006 in patients with cutaneous T-cell lymphoma. Submission is planned for the second half of 2008 for this compound. Novartis intends to explore the use of this compound in other challenging malignancies.
- **Mycograb** (antifungal) and **Aurograb** (antibacterial), acquired through the purchase of NeuTec in mid-2006, strengthened the presence of Novartis in the fast-growing market for hospital anti-infectives that address life-threatening diseases. *Mycograb* in combination with amphotericin B has demonstrated superiority in terms of clinical cure rate and Candida-related mortality. Novartis announced in November 2006 that it plans to submit additional clarification to European regulators to support the approval of *Mycograb* after receiving a negative recommendation on the submission made by NeuTec in 2005. Submission in the US is planned for 2009. *Aurograb* is being developed as an add-on therapy to vancomycin in targeting serious *staphylococcus aureus* infections, including resistant strains. Novartis is considering trials with other antibacterials as an add-on therapy. US and EU submissions for *Aurograb* are planned for 2010.

- **Prexige** (lumiracoxib) successfully completed the European Union's Mutual Recognition Procedure (MRP) in October, with all EU member states agreeing to issue approvals. European launches for this treatment for patients suffering from osteoarthritic pain of the knee and hip are planned to start in the first quarter of 2007. *Prexige* was also approved in Canada in early November. Resubmission for US approval is planned for 2007.
- **QAB149** (indacaterol), seeking to become the first once-daily long-acting beta-agonist with 24-hour bronchodilation and a fast onset of action, is being developed to treat respiratory diseases as a monotherapy and in combination with other medicines. A 52-week monotherapy Phase III trial began in the fourth quarter of 2006 in patients with chronic obstructive pulmonary disease (COPD), a condition often caused by smoking. The **QMF149** program, which combines QAB149 with the once-daily inhaled corticosteroid mometasone (Asmanex[®])³, is set to begin trials in 2007 with plans for the first regulatory submission in 2010. A Phase III monotherapy trial for QAB149 in asthma patients is part of the QMF149 program. The new **QVA149** program, also set to begin in 2007, will assess in COPD patients the potential of a once-daily fixed-dose combination of QAB149 and the once-daily inhaled long-acting muscarinic antagonist **NVA237**, which delivered positive efficacy and safety data in Phase II trials. This novel combination is expected to show superior bronchodilation compared to the individual compounds alone due to their complementary mechanisms of action.
- **RAD001** (everolimus), a novel oral inhibitor of the mTOR pathway considered a key target in oncology, has demonstrated broad clinical activity in multiple tumor types at well-tolerated and efficacious doses. A registration program is underway that includes the RADIANT-1 study in chemotherapy-refractory pancreatic islet cell tumors (pICT) and the RECORD-1 study in metastatic renal cell carcinoma. This program will be expanded in 2007 to include registration trials for refractory carcinoid tumors as well as first- and second-line pICT. RAD001 acts by directly inhibiting tumor cell growth as well as by inhibiting the formation of new blood vessels (angiogenesis). If the chemotherapy refractory pICT trial results are positive, the first submission could be as early as 2008.
- **SOM230** (pasireotide), a next-generation somatostatin analogue therapy, has completed Phase II studies in Cushing's disease, a rare disorder characterized by excessive excretion of the hormone cortisol from a pituitary adenoma (tumor), a condition for which there is no approved medical therapy. Registration studies are set to begin by year end. A registration trial in refractory carcinoid tumors is set to begin in the first quarter of 2007.
- **Tasigna** (nilotinib, formerly AMN107) has been submitted for US and EU approval as a new option for patients with resistance and/or intolerance to treatment with *Gleevec/Glivec* for certain forms of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML). A submission for this indication in Japan is expected by mid-2007. Interim Phase II results found that 46% of patients with CML resistant or intolerant to optimized *Gleevec/Glivec* therapy achieved a major cytogenic response with *Tasigna* after six months of treatment. Updated pivotal submission data will be presented at the American Society of Hematology meeting in December 2006. Both *Tasigna* and *Gleevec/Glivec* inhibit Bcr-Abl, the cause of Ph+ CML. *Tasigna* was specifically designed to be a more selective inhibitor of Bcr-Abl and its mutations. New registration studies are set to start in 2007 for *Tasigna* in gastrointestinal stromal tumors (GIST), patients with CML responding sub-optimally to other therapies and newly-diagnosed CML patients.
- **Zometa** (zoledronic acid) is on track for EU submission in the 2007 first quarter for the treatment of bone loss associated with aromatase inhibitors, a condition known as AIBL. Latest

³ In collaboration with Schering-Plough.

data from the ZO-FAST and Z-FAST studies assessing the efficacy of *Zometa* in AIBL will be presented at the San Antonio Breast Cancer Symposium in December 2006.

- Projects that have been terminated include **XBD173** (generalized anxiety disorder) and **AAE581** (osteoporosis), while **LIC477** (bipolar disorder) has been delayed.

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