NOVARTIS AG
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FORM 6-K

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Report on Form 6-K dated September 21, 2005

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Novartis AG

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- Investor Relations Release -

Novartis presents positive Phase III data on key compounds and highlights strong late-stage development pipeline

New first-in-class compounds LAF237 (diabetes) and SPP100 (hypertension) set for submission in 2006

Robust pipeline with 75 compounds in development, including 52 in Phase II/III or registration, in both specialty and general medicines

On track for five major submissions during next 12 months (LDT600, SPP100, LAF237, Lucentis, Diovan/amlodipine combination)

London, September 20, 2005 Novartis unveiled new pivotal Phase III data at a pipeline update today on two important projects LAF237 (diabetes) and SPP100 (hypertension) and intends to make regulatory submissions in 2006 for these two novel compounds with first-in-class potential.

Novartis also announced significant progress in other aspects of its industry-leading pipeline, which is comprised of 75 projects in clinical development, including 52 in Phase II, Phase III or registration and of which 46 are new molecular entities (NMEs). Key areas of development are cardiovascular & metabolism and oncology as well as neuroscience, respiratory diseases and anti-virals, with promising compounds in both general and specialty medicines.

A number of important regulatory milestones are on track to be achieved during the next 12 months, including anticipated US and EU approvals for ***Exjade*** (iron overload), ***Xolair*** (asthma) in the EU, ***Aclasta*** (Paget s disease) in the US, ***Femara*** in the US and EU for use in treating women

with breast cancer immediately following surgery (adjuvant setting) and ***Zelmac/Zelnorm*** (irritable bowel syndrome with chronic constipation) in the EU. Planned new product submissions in addition to LAF and SPP include ***Lucentis*** (age-related macular degeneration) in the EU, **LDT600** (hepatitis B) in both the US and EU as well as a new ***Diovan*** **combination with amlodipine** (hypertension).

The positive results of our two highly innovative medicines for patients with Type II diabetes and hypertension two medically important and very frequent diseases highlight the dynamic momentum in our rich and attractive pipeline. With several novel compounds in late-stage development and one of the highest R&D productivity rates in the pharmaceutical industry, we anticipate sustaining our leading position in bringing innovative therapies to patients, said Dr. Daniel Vasella, Chairman and CEO of Novartis.

Positive Phase III data support submissions for LAF237 and SPP100

Pivotal Phase III data was presented for the first time on two important late-stage compounds LAF237 and SPP100 that support plans for regulatory submissions in 2006.

LAF237 (vildagliptin), a potentially first-in-class oral DPP-IV inhibitor for the treatment of type 2 diabetes, is planned to be filed with regulatory authorities in the US in the first half of 2006. New Phase IIb/III studies showed sustained efficacy and good tolerability in treating patients with type 2 diabetes.

Phase IIb/III trial results presented at the event demonstrated strong efficacy in lowering HbA1c levels (a measure of average blood sugar levels over a two- to three-month period) and excellent tolerability without weight gain. The results also indicated the ability of LAF237 to improve and sustain pancreatic islet cell function and insulin sensitivity over a one-year period.

Consistent with earlier studies, LAF237 showed in a 12-week trial the ability to achieve in a dose-proportional manner clinically meaningful and sustained reductions of HbA1c by up to 1.6 percentage points. The trial used pioglitazone as a non-comparator positive control.

In another trial presented at the event, initial 52-week data showed a sustained reduction in HbA1c of 1.0 percentage points as a monotherapy, but narrowly missed the primary endpoint of non-inferiority versus metformin. However, the interim data from this two-year trial showed LAF237 was better tolerated than metformin, particularly with a superior gastro-intestinal tolerability profile.

LAF237 has the potential to become a first-line treatment, either as a monotherapy or in combination with other agents, for patients with type 2 diabetes, which comprises about 90% of the ever growing number of patients, estimated at currently 150 million worldwide suffering from this disease. LAF237 has demonstrated the ability to reduce HbA1c on a sustainable basis in a wide range of patients. It also showed neutral effect on body weight, good tolerability and a low incidence of hypoglycemia (low blood sugar), especially in combination with insulin.

An extensive clinical trial program is currently underway for LAF237 that aims to define the role of pancreatic islet cell protection in delaying the onset of type 2 diabetes, slowing progression and maintaining control in diabetes management and reducing cardiovascular complications. LAF237 has the potential to modify disease progression due to its positive effect on pancreatic islet cells, which produce insulin and are damaged in patients with type 2 diabetes.

SPP100 (aliskiren), the first in a new class of anti-hypertension agents called renin inhibitors, is on schedule for US regulatory submission in early 2006 after data from two Phase III clinical trials showed strong efficacy as a once-daily oral treatment, both as a monotherapy and in combination with the diuretic hydrochlorothiazide (HCTZ). Submission in the EU is planned for the fourth quarter of 2006 after completion of longer-term comparative studies.

Trial results showed SPP100 offered excellent 24-hour blood-pressure control with placebo-like tolerability, delivering statistically significant double-digit reductions in blood pressure versus placebo. Data from a Phase III dose-ranging monotherapy study confirmed statistically significant reductions in blood pressure across all doses (150 mg, 300 mg and

600 mg) along with excellent dose-proportional responder rates. Blood pressure control during a 24-hour period measured in an ambulatory setting was excellent with a trough-to-peak ratio of close to 100% at the 300 mg dose.

Results of another Phase III trial that combined SPP100 with HCTZ showed additional blood-pressure-lowering benefits and improved responder rates relative to placebo and was also well tolerated.

Data from clinical trials combining the use of SPP100 with two other anti-hypertension agents an angiotensin-converting-enzyme inhibitor (ACE inhibitor) and a calcium channel blocker (CCB) are planned to be presented in 2006. Three major outcome morbidity and mortality studies/programs are planned to start in 2006 to ensure an extensive profiling program of SPP100 compared to other anti-hypertensives, with data expected in 2011 and beyond, while three surrogate outcome studies to support end-organ protection concepts are scheduled to begin reporting results in the second half of 2006.

SPP100, developed in collaboration with Speedel, has the potential to offer improved end-organ protection due to its inhibition of renin activity (an emerging indicator of cardiovascular risk). This compound is being explored in an extensive profiling program compared to other antihypertensives and through major clinical studies that are planned to be available at launch.

This new data for SPP100 and LAF237 show that both novel compounds have the potential to transform the way in which physicians treat two fast-growing diseases hypertension and diabetes that are increasingly being found together in many patients. Patients with multiple cardiovascular risk factors, such as hypertension or type 2 diabetes, have a substantially increased risk of hospitalization or death, said Dr. Joerg Reinhardt, Head of Development at Novartis Pharma AG. We are committed to offering a range of medicines that help physicians better address the increasing challenge of treating patients with these diseases that are becoming a public health challenge in many countries.

Helping patients with cardiovascular and metabolic diseases

Novartis has a comprehensive portfolio of cardiovascular products both in the market (***Diovan*** and ***Lotrel***) as well as in development (such as LAF237 and SPP100), to help physicians address the increasing convergence of hypertension, dyslipidemia and diabetes in patients worldwide. Other compounds in development include **APP018** (D-4F), an oral Apo A-1 mimetic in trials for atherosclerosis disease, as well as compounds interacting with the **SCD-1** target as an anti-obesity treatment to complement the development focus on hypertension, diabetes, athero-dyslipidemia and metabolic syndrome/obesity.

Diovan is the fastest-growing major anti-hypertension medicine in the world, approaching USD 4 billion in annual sales based on clinical data supporting its best-in-class efficacy as an angiotensin-receptor-blocker (ARB) and unique cardioprotective profile. The NAVIGATOR trial, set to report in 2009, is the largest outcomes trial ever conducted on the prevention of cardiovascular disease and type 2 diabetes in patients with impaired glucose tolerance.

Expanding the potential of *Diovan*, Novartis plans to submit in 2006 for regulatory approval a **fixed-dose combination of *Diovan* with amlodipine**, a calcium channel blocker (CCB). This would mark the first combination of a CCB with an ARB, offering a once-daily treatment with a dual mechanism of action that combines the benefits of both drugs in one pill. The use of combinations of therapies is becoming more common in the treatment of hypertension. Novartis

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presented data at the event that showed how compliance with treatment goals can be improved using other fixed-dose combination products, such as *Lotrel*, a combination of the ACE inhibitor lotensin and amlodipine. Combinations of *Diovan* with other anti-hypertension agents, including SPP100, are in clinical development.

Late-stage pipeline highlights

Industry experts have consistently ranked Novartis as having one of the best pipelines, focusing on many compounds that have the potential to become a new standard of care and the first to market in their respective classes.

The priority development projects include:

***Aclasta*(1)** (zoledronic acid 5 mg) was recently shown in a head-to-head Phase III study published in the *New England Journal of Medicine* to offer superior efficacy, faster onset of action and a longer period of remission compared to risedronate, the current oral standard of care in Paget s disease. *Aclasta* was first launched in Germany in May 2005, and other launches are expected during 2005 and 2006. The FDA issued an approvable letter for this product for the treatment of Paget s disease in March 2005, and a complete response was submitted in August. Phase III trials are underway to demonstrate the benefits of *Aclasta* as a once-yearly treatment for various forms of osteoporosis, with submissions to US and EU regulatory authorities planned for 2007.

AMN107, a novel investigational oral compound being developed as a new treatment for advanced chronic myeloid leukemia (CML) patients, is planned to be submitted for regulatory approval in 2007. Enrollment in a pivotal Phase II study of patients with CML resistant to *Gleevec/Glivec* began in April 2005, with a Phase III study in chronic phase CML patients initiating treatment planned to begin in the first quarter of 2006. AMN107 further expands the Novartis franchise for helping patients with CML and GIST (gastrointestinal stromal tumors).

Exjade (deferasirox) (ICL670) is awaiting US regulatory approval after being granted a six-month priority review in June 2005. It was shown in clinical studies (20-30 mg/kg/day) to be effective in removing excess iron from repeated blood transfusions and was submitted for regulatory approval in the US, EU and Switzerland in April 2005. It has orphan drug status in the US and EU. As a once-daily oral formulation, *Exjade* offers the potential to improve treatment compliance and quality of life of patients with chronic transfusional iron overload a potentially life-threatening condition compared to deferoxamine, the current cumbersome infusion therapy standard of care.

Femara (letrozole), a leading therapy for early and advanced breast cancer in postmenopausal women, was submitted for US and EU regulatory approval for use immediately after surgery (adjuvant setting). The FDA has granted priority review for this new indication, with a decision expected by the end of 2005. *Femara* was also recently submitted for approval in Japan for treatment of postmenopausal women with breast cancer, and a decision is expected by the end of 2005 or in early 2006.

FTY720 has demonstrated sustained benefits and good tolerability as an oral treatment for patients with relapsing multiple sclerosis (MS), in the extension of a Phase II trial to 12

(1) Zoledronic acid (5 mg) is authorized to be marketed under the name Aclasta in Europe and is awaiting US approval of a different trademark.

months. Detailed results will be presented at the ECTRIMS/ ACTRIMS meeting on October 1. Six-month data from the Phase II trial showed that FTY720 significantly reduced the rate of clinical relapses by more than 50% in people with MS compared to placebo. FTY720 also reduced inflammatory disease activity, as measured by magnetic resonance imaging (MRI), by up to 80% over six months compared to placebo. Novartis is discussing its Phase III program with regulatory authorities, which is expected to be launched by the end of 2005. Over two million worldwide are estimated to suffer from MS, which is the leading cause of neurological disability in young adults, according to the Multiple Sclerosis International Federation. Currently approved therapies have limited clinical effect and require frequent injections ranging from daily to weekly. If confirmed in larger-scale Phase III studies, FTY720 could represent a major and long-awaited breakthrough for MS patients.

Gleevec/Glivec (imatinib mesylate), indicated for all stages of Philadelphia chromosome positive (Ph+) chronic myeloic leukemia (CML) and certain forms of gastro-intestinal stromal tumors (GIST), has recently received approval from the EMEA for increasing the average daily dose to 600 mg or 800 mg from 400 mg in patients with chronic phase CML and GIST. Gleevec is on track to be submitted by the end of 2005 in the US, EU and Japan as a treatment for Ph+ acute lymphoid leukemia (ALL) and other rare diseases. A registration program in glioblastoma multiforme, the most common and aggressive of the primary brain tumors, has been initiated.

LDT600 (telbivudine) successfully reached its primary composite efficacy endpoint of therapeutic response in the Phase III GLOBE registration trial in chronic hepatitis B. Full one-year data from this trial will be presented at the American Association for the Study of Liver Diseases (AASLD) on November 14. All key filings for LDT600 are planned to be completed by the end of the 2006 first quarter. This once-daily treatment for hepatitis B infections, estimated to affect about 350 million people worldwide, is being developed in collaboration with Idenix Pharmaceuticals.

Lucentis (ranibizumab), the potential new gold standard treatment for wet age-related macular degeneration (AMD), the leading cause of blindness in people over age 50, has shown strong efficacy and a good safety profile in recent clinical trials. The Phase III MARINA study reported unprecedented results in maintaining and/or improving vision in patients with either the minimally classic or the occult form of wet AMD, FOCUS, a Phase I/II clinical study investigating the safety and efficacy of Lucentis in combination with Visudyne compared to Visudyne alone in patients with predominantly classic wet AMD, met its primary efficacy endpoint of maintaining or improving vision. Data from the second Phase III study, ANCHOR, which is assessing Lucentis versus photodynamic therapy in the treatment of the predominantly classic form of wet AMD, are expected in the fourth quarter of 2005. Lucentis is being developed with Genentech, which retains the right to develop and market the product in North America. Regulatory submission is expected in 2006 in the EU.

Prexige (lumiracoxib) was launched in Brazil in August 2005 for the treatment of osteoarthritis and acute pain. Additional launches of this new COX-2 selective inhibitor are anticipated for other markets, including the United Kingdom, by the end of the year. The application for EU regulatory approval is planned for early 2006, while re-submission in the US is planned for 2007. Prexige is already approved in 22 countries.

QAB149 (indacaterol), a long-acting beta-agonist, may provide a new standard of care in patients with asthma and chronic obstructive pulmonary disease (COPD) based on Phase II data showing a rapid onset of action and 24-hour control. QAB149 has the potential to become the first once-daily beta agonist by offering significant therapeutic potential for patients with asthma and COPD, either as a single agent or in combination with other Novartis respiratory compounds, such as the long-acting anti-muscarinic agent NVA237. Phase III trials are planned to start in early 2006, with regulatory submissions expected in 2007. Several options for combination products are currently being evaluated in parallel.

Xolair (omalizumab), a first-in-class therapy for the treatment of severe persistent allergic asthma, is awaiting EU regulatory approval after the Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion in July 2005. First approved in the US in 2003 with partner Genentech, Xolair is set to become the first humanized antibody to be approved for the treatment of asthma in Europe, representing a highly innovative approach to controlling this disease.

Zelnorm/Zelmac (tegaserod), is currently under review by the EMEA for approval in the EU for the treatment of irritable bowel syndrome with constipation (IBS-C). Two Phase III clinical trials with Zelnorm, which was approved in the US in 2004, are currently ongoing for the treatment of dyspepsia, and both are planned to be completed in 2006. Data from a proof-of-concept study in GERD (gastroesophageal reflux disease) is being analyzed following the recent completion of the study.

Novartis plans joint research partnership with FDA

Novartis is planning to partner with the US Food and Drug Administration on three projects as part of the FDA s major effort called the Critical Path Initiative to modernize the medical product development process.

The first project will seek to identify and evaluate new manufacturing methods designed to assure quality. A second project will involve identifying a mechanism by which biomarkers can be validated for regulatory use in developing new drug therapies, while a third project will seek to find a regulatory pathway for the simultaneous development of a particular therapy and a diagnostic test kit that would enable the identification of patients who are most likely to benefit from the particular therapy.

Disclaimer

The foregoing release contains certain forward-looking statements that can be identified by terminology such as set for submissions , on track, intends, anticipate , plans , planned , potential , on schedule , scheduled , set to report , would mark , expected , potentially , wi anticipated , may provide , or similar expressions, or by express or implied discussions regarding the potential that any of the new products described above will be approved for sale in any market; regarding the potential that any existing product will be approved in any additional markets or will be approved for any additional indication in any market; or regarding any potential future revenues from any such products or indications. Such forward-looking statements 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 of the new products described in this release will be approved for sale in any market; that any existing product will be approved in any additional markets or for any additional indication; or that any such product will achieve any particular sales level. In particular, management s expectations could be affected by, among other things, uncertainties relating to clinical trials; new clinical data, or

additional analysis

of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; as well as other risks and factors referred to in the Company 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 anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, the Novartis group of companies businesses achieved sales of USD 28.2 billion and a pro forma net income of USD 5.8 billion. The group invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis group companies employ approximately 83,700 people and operate in over 140 countries around the world. For further information, please consult http://www.novartis.com.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Novartis AG

Date: September 21, 2005

By: /s/ MALCOLM B. CHEETHAM

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