NOVARTIS AG
Form 6-K
September 21, 2012

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 or 15d-16 OF

THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated September 21, 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F: x Form 40-F: o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: o **No**: x

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: o **No**: x

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o **No**: x

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis announces two CHMP positive opinions for new indications of Galvus® and Eucreas® combined with other diabetes treatments

- *Positive opinion for the use of vildagliptin, with or without metformin, in combination with a stable dose of insulin(1)*
- *Additional positive opinion for the use of vildagliptin in combination with a sulphonylurea and metformin(1)*
- *Positive opinions open the way for new treatment options for patients unable to reach their blood sugar goals*

Basel, September 21, 2012 Novartis announced today that the European Medicines Agency s Committee for Medicinal Products for Human Use (CHMP) has issued two positive opinions for new indications for the use of Galvus® (vildagliptin) and Eucreas® (vildagliptin and metformin) in combination with other treatments for type 2 diabetes patients(1).

The first positive opinion was for vildagliptin in combination with insulin, with or without metformin, for patients with type 2 diabetes when diet, exercise and a stable dose of insulin do not result in glycemic control(1). The second positive opinion was for vildagliptin in triple combination with metformin and a sulphonylurea for the treatment of type 2 diabetes when diet and exercise plus dual therapy with these two agents do not provide adequate glycemic control(1).

These CHMP positive opinions are important milestones in our efforts to offer physicians and patients effective and generally well-tolerated additional treatment options to help reach and maintain blood sugar goals, says David Morris, Primary Care Franchise Head of Development, Novartis Pharmaceuticals.

The CHMP positive opinion for the use of vildagliptin in combination with insulin was based on a 24-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group trial (n=449) which demonstrated that vildagliptin 50 mg administered twice daily in combination with insulin, with or without metformin, reduced blood sugar levels (HbA1c) versus placebo (-0.7%; P<0.001)(2). The addition of vildagliptin was weight neutral and resulted in a similar incidence of hypoglycemia versus placebo(2).

The CHMP positive opinion for the use of vildagliptin in combination with metformin and a sulphonylurea was based on a 24-week, randomized, double-blind, placebo-controlled, parallel-group trial (n=318)(1). The study demonstrated that vildagliptin 50 mg twice-daily in combination with metformin and a sulphonylurea reduced blood sugar levels (HbA1c) versus placebo (-0.8%; P<0.001)(1). Five times as many patients reached their blood sugar level goal versus placebo (28.3% for vildagliptin versus 5.6% for placebo; P<0.001)(1). The addition of vildagliptin was weight neutral versus placebo and had a low incidence of hypoglycemia(1). As part of the positive opinion, it was noted that sulphonylureas are known to cause hypoglycemia so physicians may consider a lower dose of sulphonylurea to reduce this risk when combining treatments(1).

Upon approval, vildagliptin in combination with insulin, with or without metformin, and vildagliptin in combination with metformin and a sulphonylurea will offer new treatment options for patients unable to reach blood sugar goals, with a low risk of hypoglycemia while also achieving weight neutrality(1),(3).

About diabetes

Diabetes is one of the world s greatest healthcare challenges, affecting 366 million people globally and killing one person every seven seconds(4). The obesity epidemic and an aging world population are contributing to the escalating incidence of type 2 diabetes and by 2030 it is projected that more than half a billion people will be diagnosed with the disease(4). Type 2 diabetes accounts for 90 percent of all cases of the disease(5).

About Galvus®

Galvus® (vildagliptin) is a dipeptidyl peptidase-4 (DPP-4) inhibitor, a class of oral diabetes medications that enhance the body s natural ability to control blood sugar. The Galvus® (vildagliptin) safety and efficacy profile has been established in a comprehensive clinical trial program that included more than 15,000 type 2 diabetes patients(6).

Galvus® (vildagliptin) is approved in more than 100 countries across Europe, Asia Pacific, Africa and Latin America. It is indicated for the treatment of type 2 diabetes as a monotherapy and in combination with metformin, a sulphonylurea, a thiazolidinedione or insulin(6). Specific indications vary by country.

About Eucreas/Galvus® Met

Eucreas®/Galvus® Met (vildagliptin and metformin) is a single-pill fixed-dose combination of Galvus® (vildagliptin) and metformin. Eucreas®/Galvus® Met (vildagliptin and metformin) is approved in more than 80 countries across Europe, Asia Pacific, Africa and Latin America for the treatment of patients with type 2 diabetes who are unable to control blood sugar with metformin alone(7). Specific indications vary by country.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as positive opinion, open the way, milestones, will, projected, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Novartis vildagliptin products or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Novartis vildagliptin products to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Novartis vildagliptin products will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that such products will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Novartis vildagliptin products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; unexpected manufacturing issues; the impact that the foregoing factors could have on the values attributed to the Novartis 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 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 provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2011, the Group achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 126,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

References

(1) Novartis Pharma AG data on file.

(2) Lukashevich V et al. Vildagliptin combined with insulin reduces HbA1c without increasing risk of hypoglycemia and weight gain in patients with type 2 diabetes mellitus. Poster presented at the 72nd American Diabetes Association; June 8-12, 2012; Philadelphia, PA, USA. Poster # 995-P.

(3) Inzucchi SE et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach. Position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetologia. 2012;55:1577-1596.

(4) International Diabetes Federation. Global diabetes plan. http://www.idf.org/sites/default/files/Global_Diabetes_Plan_Final.pdf. Accessed September 7, 2012.

(5) International Diabetes Federation. Types of diabetes. http://www.idf.org/types-diabetes. Accessed September 7, 2012.

(6) Galvus Summary of Product Characteristics (SmPC).

(7) Eucreas Summary of Product Characteristics (SmPC).

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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, 2012	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting