NOVARTIS AG
Form 6-K
July 27, 2018

UNITED STATES

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 July 27, 2018

(Commission File No. 1-15024)

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Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

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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: Form 40-F:

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: **No**:

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: **No**:

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: **No**:

Media Release Medienmitteilung Communiqué Aux Médias

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Sandoz receives European Commission approval for biosimilar Hyrimoz® (adalimumab)

- Biosimilar Hyrimoz® (adalimumab) approved for use in all same indications as reference medicine†* including rheumatology, gastroenterology and dermatology
- *Early therapeutic intervention is essential in rheumatoid arthritis, supporting urgency of treatments like Hyrimoz*
- *Fourth Sandoz biosimilar approved in Europe** in past 18 months, and seventh in total, underscoring Sandoz commitment to making access happen through a robust portfolio*

Holzkirchen, July 27, 2018 – Sandoz, a Novartis division and the pioneer and global leader in biosimilars, today announced that the European Commission (EC) granted marketing authorization to biosimilar Hyrimoz® (adalimumab) for use in all indications of the reference medicine†*, including rheumatoid arthritis, plaque psoriasis, Crohn's disease, uveitis and ulcerative colitis.[1],[2]

Rheumatoid arthritis alone affects up to 1% of people in the European Union. Patients with moderate to severe rheumatoid arthritis can have chronic inflammation that causes fatigue, pain and joint stiffness. Symptoms can be reversible with appropriate treatment, however the joint damage and the resulting disability are permanent.3 The introduction of biosimilars has been shown to improve access to advanced treatment options, such as biologic medicines.[4]

“We believe in making access happen for patients who are suffering from chronic inflammatory diseases. Earlier and expanded access to important, disease-modifying, biologic medicines can fundamentally change how patients manage their health,” said Stefan Hendriks, Global Head of Biopharmaceuticals, Sandoz. “Biosimilars such as Hyrimoz can also play a transformational role in healthcare system sustainability – so we look forward to making Hyrimoz, and other important biosimilar medicines, broadly available.”

The approval was based on a comprehensive data package comprising analytical, preclinical and clinical research demonstrating that Hyrimoz matches the reference biologic in terms of safety, efficacy and technical quality. A randomized, double-blind, three-arm, parallel study confirmed the pharmacokinetics, immunogenicity and safety of Hyrimoz. The study met the primary endpoint, demonstrating bioequivalence for all primary pharmacokinetic parameters. A Phase III confirmatory safety and efficacy study (ADACCESS) demonstrated therapeutic equivalence in the sensitive indication of patients with moderate to severe chronic plaque-type psoriasis, with a similar safety and immunogenicity profile to the reference biologic. No meaningful clinical differences were observed.[5-7]

Sandoz is well-positioned to lead the biosimilars industry based on its experience and capabilities in development, manufacturing and commercialization. Hyrimoz is the company’s seventh approved biosimilar medicine in Europe. Additional biosimilars for oncology and immunology indications are expected to launch globally across major regions by 2020.

About Hyrimoz® (adalimumab)

Hyrimoz is an inhibitor of tumor necrosis factor (TNF), a protein that is overproduced in certain autoimmune conditions—including rheumatoid arthritis, plaque psoriasis, Crohn's disease and ulcerative colitis—causing inflammation and tissue destruction in joints, mucosa or skin. In some cases of autoimmune disease, the immune system damages the body’s own tissues. Hyrimoz can be a potentially appropriate treatment option for certain patients across a variety of indications. Hyrimoz works by targeting and blocking the protein that contributes to disease symptoms.[1]

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Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potentially,” “plan,” “expected,” “proposed,” “potential,” “can,” “will,” “look forward,” “believe,” “committed,” “investigational,” “portfoli similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labelling for the investigational or approved biosimilar products described in this press release, or regarding potential future revenues from Hyrimoz and such other biosimilar products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward- looking statements. There can be no guarantee that Hyrimoz or the other investigational or approved biosimilar products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that, if approved, such other biosimilar products will be approved for all indications included in the reference product’s label. Nor can there be any guarantee that Hyrimoz or such other products will be commercially successful in the future. In particular, our expectations regarding Hyrimoz and such other products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. 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 Sandoz

Sandoz is a global leader in generic pharmaceuticals and biosimilars. As a division of the Novartis Group, our purpose is to discover new ways to improve and extend people’s lives. We contribute to society’s ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine. Our

portfolio of approximately 1,000 molecules, covering all major therapeutic areas, accounted for 2017 sales of USD 10.1 billion. In 2017, our products reached well over 500 million patients. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area.

Sandoz is on Twitter. Sign up to follow @Sandoz_global at http://twitter.com/Sandoz_Global.

Follow our blog at www.sandoz.com/makingaccesshappen.

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References:

1. European Medicines Agency. Hyrimoz. Key Facts. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004320/smops/Positive/human_smop_001301.jsp&mid=WC0b01ac058001d127&source=homeMedSearch&category=human. Accessed June 19, 2018.
2. European Medicines Agency. Hyrimoz. Summary of Product Characteristics: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004320/smops/Positive/human_smop_001301.jsp&mid=WC0b01ac058001d127.
3. European Medicines Agency.http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/12/news_detail_002667.jsp&mid=WC0b01ac058004d5c1. Accessed July 5, 2018.
4. European Commission Consensus paper – What you need to know about biosimilar medicines: http://ec.europa.eu/DocsRoom/documents/8242. Accessed July 2, 2018.
5. Blauvelt A. A randomized, double-blind, multicenter study to compare the efficacy, safety, and immunogenicity of a proposed adalimumab biosimilar (GP2017) with originator adalimumab Poster #5224 presented at the 2017 American Academy of Dermatology (AAD) Annual Meeting, 3-7 March 2017.
6. Blauvelt A. Long-Term Efficacy, Safety and Immunogenicity Results from a Randomized, Double-Blind, Phase III Confirmatory Efficacy and Safety Study Comparing GP2017, a Proposed Biosimilar, with Reference Adalimumab [abstract]. Arthritis Rheumatol. 2017; 69 (suppl 10). American College of Rheumatology (ACR) Annual Meeting, US, 3-9 November 2017.
7. Jauch-Lembach J. Randomized, Double-Blind, Single-Dose, Three-Arm Parallel Trial to Determine the Pharmacokinetics and Safety of GP2017, EU- and US-Adalimumab in Healthy Male Subjects [abstract]. Arthritis Rheumatol. 2017; 69 (suppl 10). American College of Rheumatology (ACR) Annual Meeting, US, 3-9 November 2017.

†Humira® (adalimumab) is marketed by AbbVie Deutschland GmbH & Co. KG in Europe and Humira® is a registered trademark of AbbVie Biotechnology, Inc.

*Hyrimoz is only available as 40 mg pre-filled syringe / pre-filled pen. Thus, it is not possible to administer Hyrimoz to pediatric patients that require less than a full 40 mg dose. If an alternate dose is required, other adalimumab products offering such an option should be used.

**European Commission decisions on the authorization of medicines are valid throughout the 31 countries of the European Economic area, which comprises the 28 member countries of the European Union plus Norway, Iceland and Liechtenstein. That governing body bases its decisions on scientific assessments by the Committee for Medicinal Products for Human Use (CHMP), a subgroup of the European Medicines Agency (EMA).

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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: July 27, 2018 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Head Group Financial
Title: Reporting and
Accounting