

NOVARTIS AG
Form 6-K
March 21, 2014

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 March 21, 2014

(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:

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Form 20-F: ☒ **Form 40-F:** ☐

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Yes: ☐ **No:** ☒

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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:** ☒

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

UK recommends Novartis Bexsero® vaccine for inclusion in National Immunisation Programme to help protect against devastating meningitis B

- *Following further review of evidence, JCVI recommends routine vaccination of infants against meningitis B, the leading cause of meningitis in Europe(1),(2)*
- *UK will introduce a nationwide vaccination campaign with Bexsero as soon as possible; once implemented, parents will have free access through the NHS*
- *Novartis is committed to working with UK public health officials to ensure implementation of this recommendation as early as summer 2014*

Basel, 21 March, 2014 Novartis announced today that the Joint Committee on Vaccination and Immunisation (JCVI) in the UK has recommended the inclusion of Bexsero® (Meningococcal Group B Vaccine [rDNA, component, adsorbed]) in the National Immunisation Programme(1). According to the recommendation, Bexsero should be routinely used in infants from two months of age to help protect against meningococcal serogroup B (meningitis B)(1). The implementation will be carried out by the Department of Health through the National Health Service (NHS), following the public procurement process.

Today's decision by the UK authorities brings tremendous relief to many parents and families who have lost loved ones to meningitis, said Andrin Oswald, Division Head, Novartis Vaccines. At Novartis, it took us over 20 years of hard work to get to this point. Protecting infants who are the most vulnerable will be a great achievement. It is also a strong motivator for us to continue our efforts to protect all children and adolescents against this devastating disease, in the UK and elsewhere in the world.

Meningitis B is a rare but aggressive and often deadly disease(3); it is the leading cause of meningococcal disease and septicemia in Europe(2). Meningitis B can kill or cause serious life-long disabilities within 24 hours of onset, leaving little time for intervention(3). Like infants, adolescents are also at an increased risk for contracting meningitis and have a high fatality rate from the disease(4),(5). Approximately 3,200 people in the UK are affected by bacterial meningitis and septicemia each year, with meningitis B responsible for more than half of those cases(6). Vaccination is therefore the best defense against this aggressive disease.

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I applaud the JCVI for taking the right decision to make this life-saving vaccine available to babies and am delighted that the UK is once again leading the way in meningococcal disease prevention. However I would urge that toddlers and adolescents should also be offered protection, said Dr Nelly Ninis, Consultant Pediatrician, London. No child should suffer the devastation of a preventable disease, especially one that can be fatal within hours, and leave many of its survivors maimed and impacted for life.

Bexsero is the only licensed broad coverage vaccine approved in Europe, Canada and Australia for all vulnerable age groups from two months to help protect against meningitis

B(7),(8),(9). It was also approved for use in the US under a treatment Investigational New Drug (IND) designation as part of vaccination programs at Princeton University and the University of California Santa Barbara (UCSB)(10),(11). The recent outbreaks of meningitis B in the US demonstrate the dynamic and unpredictable nature of this disease and the need for broad coverage protection through vaccination(12). Novartis continues to work with health authorities around the world where meningitis B remains an unmet public health need to support broad and timely access to the vaccine.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as recommends, will, as soon as possible, committed, to ensure, recommendation, recommended, should, to continue, can, would, continues, remains, or similar terms, implied discussions regarding potential additional marketing or reimbursement approvals for Bexsero, or regarding potential future revenues from Bexsero. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 Bexsero will be submitted or approved for sale or reimbursement in any additional markets, or at any particular time. Nor can there be any guarantee that Bexsero will be commercially successful in the future. In particular, management's expectations regarding Bexsero could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; global trends toward health care cost containment, including ongoing pricing pressures; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; unexpected manufacturing issues, 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 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 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 136,000 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) JCVI position statement on use of Bexsero® meningococcal B vaccine in the UK: March 2014.
- (2) ECDC European Centre for Disease Prevention and Control. Annual epidemiological report 2012. Invasive meningococcal disease. Available at: <http://ecdc.europa.eu/en/publications/Publications/Annual-Epidemiological-Report-2012.pdf>. Accessed March 2014.
- (3) World Health Organization. Meningococcal meningitis factsheet. Nov 2012. Available at: <http://www.who.int/mediacentre/factsheets/fs141/en/>. Accessed March 2014.
- (4) Health Protection Agency. Epidemiological data. Available at: www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/MeningococcalDisease/EpidemiologicalData/. Accessed March 2014.

- (5) Harrison et al, Invasive Meningococcal Disease in Adolescents and Young Adults. Journal of the American Medical Association. August 2001, Vol 286, No. 6 Available at: <http://jama.jamanetwork.com/article.aspx?articleid=194084>. Accessed March 2014.
- (6) Meningitis Research Foundation, Meningitis and Septicaemia UK Facts & Figures. Available at: <http://www.meningitis.org/facts>. Accessed March 2014.
- (7) Bexsero (Meningococcal Group B Vaccine [rDNA, component, adsorbed]). Summary of Product Characteristics (SmPC). 2013. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002333/WC500137881.pdf. Accessed March 2014.
- (8) Summary Basis of Decision (SBD): Bexsero - 2014 - Health Canada. Available at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd_smd_2014_bexsero_147275-eng.php. Accessed March 2014.
- (9) Australian Public Assessment Report for Multi-Component Meningococcal B vaccine. Available at: <http://www.tga.gov.au/pdf/auspar/auspar-meningococcal-131031.pdf>. Accessed March 2014.
- (10) Centers for Disease Control and Prevention. Princeton University Meningococcal Disease Outbreak. December 2013. Available at: <http://www.cdc.gov/meningococcal/outbreaks/princeton.html>. Accessed March 2014.
- (11) Centers for Disease Control and Prevention. University of California, Santa Barbara Meningococcal Disease Outbreak. January 2014. Available at: <http://www.cdc.gov/meningococcal/outbreaks/ucsb.html>. Accessed March 2014.
- (12) Harrison LH, Trotter CL, Ramsay ME. Global epidemiology of meningococcal disease. Vaccine. 2009;27 Suppl 2:B51 B63.

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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: March 21, 2014

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
Title: Head Group Financial
Reporting and Accounting
