NOVARTIS AG
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SECURITIES AND EXCHANGE COMMISSION

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FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

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THE SECURITIES EXCHANGE ACT OF 1934

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(Commission File No. 1-15024)

Novartis AG

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Pivotal study published in *JAMA* confirms potential of Novartis candidate vaccine Bexsero® to help protect infants against devastating meningococcal serogroup B disease

- *Data previously presented at ESPID annual meeting add to the body of evidence showing that Bexsero can help protect all vulnerable age groups*

- *Study including more than 1,800 infants showed Bexsero induces robust immune response when given alone or with other routine vaccines in different vaccination schedules(1)*

- *Current vaccines do not broadly protect against MenB which is easily misdiagnosed and can kill within 24 hours; infants are at highest risk(2)*

Basel, February 7, 2012 The Journal of the American Medical Association (JAMA) published a study today that shows Bexsero induced a robust immune response against meningococcal B disease in the vast majority of infants vaccinated. These results also show that Bexsero can fit into various vaccination schedules in the first year of life when the likelihood of contracting this often-deadly disease is greatest. The study also demonstrated that Bexsero has an acceptable tolerability profile.

These data were first presented in 2011 at the 29th Annual Meeting of the European Society of Paediatric Infectious Diseases (ESPID)(3).

The publication of these results in JAMA add to the growing body of evidence supporting Bexsero s potential to help protect all age groups, from infants to adults, against this devastating disease. said Andrin Oswald, Head of Novartis Vaccines and Diagnostics Division. Bexsero holds great promise in providing a solution to a major public health concern the lack of a routine vaccine providing broad protection against MenB,

Meningococcal disease is feared and often deadly(3); it is easily misdiagnosed, can kill within 24 hours of onset and may cause serious, life-long disabilities(2),(6),(4). The majority of cases in some of the developed world are due to serogroup B (MenB)(5), with a disproportionate disease burden in infants(5). In general, approximately one in ten of people who contract meningococcal disease will die despite appropriate treatment(2),(6),(7) of the survivors, around one in five suffers permanent disabilities such as brain damage, hearing loss, or learning

difficulties(6),(7). Meningococcal disease most commonly affects otherwise healthy persons, and in many cases physicians cannot diagnose and treat an infected child soon enough to avoid serious outcomes, therefore prevention through vaccination is the best means to counter meningococcal disease.

The development of a broadly protective vaccine against MenB disease has been a formidable challenge and, if successful, would represent an enormous step forward in the prevention of childhood meningitis, said Dr Matthew Snape, Consultant in Vaccinology and General Paediatrics, University of Oxford, UK. This study provides important data

on how well infants immune systems respond to this new MenB vaccine when given in a variety of schedules. This information is vital when considering how the vaccine could be incorporated into different immunization regimens around the world.

Study Design and Results

This pivotal Phase IIb open-label immunogenicity study(1) randomized 1,885 infants to receive Bexsero at 2, 4, 6 months together with routine infant vaccines; at 2, 4, 6 months with routine vaccines given separately at 3, 5, 7 months; or at 2, 3, 4 months together with routine infant vaccines. A control group received the routine vaccines only at 2, 3, 4 months. The routine vaccines used were 7-valent pneumococcal glycoconjugate vaccine and a combined diphtheria, tetanus, acellular pertussis, inactivated polio, hepatitis B and *Haemophilus influenzae* type b vaccine.

Immune response was measured using the human serum bactericidal antibody (hSBA) assay with a titer $\geq$ 1:5, which is the accepted level that correlates with protection. The study met all of its primary endpoints, and showed that the majority of infants vaccinated with Bexsero, at either dosing schedule with or without routine vaccines, achieved hSBA $\geq$ 1:5 against all vaccine antigens in tested MenB strains (H44/76, 5/99, NZ98/254). More than 99% of participants receiving Bexsero at 2, 4, 6 months (with or without routine vaccines) or at 2, 3 and 4 months (with routine vaccines) developed hSBA titers $\geq$ 1:5 against the reference strains 44/76 and 5/99. For NZ98/254 the $\geq$ 1:5 result was reached or exceeded in 79% (2, 4, 6 months with routine vaccines), 87% (2, 4, 6 months without routine vaccines) and 81% (2, 3, 4 months with routine vaccines) of patients on the corresponding schedules.

The immune response to routine vaccine antigens when co-administered with Bexsero was similar to that in the control group(1), except for slightly lower immune responses to pneumococcal serotype 6B and pertactin, comparable with other licensed vaccines. The data also showed that Bexsero, when administered alone, had a reactogenicity profile that was comparable to those of the routine vaccines(1). Fever, which is a common event following routine childhood immunizations, was observed more frequently in infants who received Bexsero together with routine infant vaccines compared to infants receiving routine vaccines alone(1). Fever was generally mild-to-moderate and of short duration, with more than 95% of cases resolving within 24-48 hours(1).

Bexsero is the result of more than 20 years of pioneering research in the fight to protect infants and other populations at risk of infection from MenB(6),(7). To address the unpredictable and changing nature of meningococcus bacteria over time, Bexsero comprising four key components that independently are highly immunogenic(8) was designed to protect against the majority of disease-causing strains worldwide. The immunogenicity and tolerability of Bexsero has been demonstrated in large Phase III clinical trials involving more than 8,000 infants, adolescents and adults with post-vaccination reactions comparable to those of other routine vaccines(4),(9). In December 2010, a Marketing Authorization Application (MAA) for Bexsero was submitted in Europe and in other countries, including a proposed infant vaccination schedule consisting of three doses for the primary series. Regulatory action is expected later in 2012.

The study was published in the February 8, 2012 issue of JAMA(1) with the title of Immunogenicity and tolerability of recombinant meningococcal serogroup B vaccine administered with or without routine infant vaccinations according to different immunization schedules: A randomized controlled trial by Nicoletta Gossger MD, Matthew D Snape FRCPCH MD, et al.

About Bexsero

The Novartis Bexsero vaccine (also known as 4CMenB) was developed using a pioneering approach known as reverse vaccinology(9). This was necessary because the approach used to produce a conjugate meningococcal vaccine against serogroups A, C,

W-135 and Y could not be used for MenB. The capsular polysaccharide of MenB is identical to a polysaccharide component present in the human body and is therefore not immunogenic. In contrast to conventional methods of developing vaccines, reverse vaccinology was used to decode the genetic makeup (genome sequence) of MenB and select those proteins that were most likely to be broadly effective vaccine candidates(9). Bexsero contains multiple components, which are highly immunogenic independently and, taken together, have the potential to protect against a broad range of disease-causing MenB strains(11). To date, more than 8,000 infants, toddlers, and adults have been enrolled in studies of Bexsero(1),(10),(11),(12),(13),(14). Bexsero is not currently licensed for use in any country.

Licensed vaccines are available to protect against meningococcal disease caused by serogroups A, C, W-135 and Y(7); however, MenB remains an important unmet public health challenge(5).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as would, could, will, promise, potentia proposal, or similar expressions, or by express or implied discussions regarding potential future marketing approvals for Bexsero or regarding potential future revenues from Bexsero. 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 Bexsero to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Bexsero will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that Bexsero will achieve any particular levels of revenue 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; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; government, industry and general public pricing pressures; unexpected manufacturing issues; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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 s continuing operations 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 124,000 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.

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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:	February 7, 2012	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting