

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG****Novartis Bexsero<sup>®</sup> vaccine approved by FDA for the prevention of meningitis B, the leading cause of bacterial meningitis in the US**

- *With today's approval, Bexsero is now licensed in 37 countries; since first approval in Europe, over 1 million doses have been distributed worldwide*
- *Bexsero's two-dose regimen offers a flexible dosing schedule, with the first and second doses administered at least one month apart<sup>1</sup>*
- *Access to meningitis B vaccines for all adolescents and young adults will be critical to help prevent this potentially deadly and unpredictable disease<sup>2,3</sup>*

**Basel, January 23, 2015** – Novartis announced today that the US Food and Drug Administration (FDA) has granted accelerated approval of Bexsero<sup>®</sup> (Meningococcal Group B Vaccine [recombinant, adsorbed]) for active immunization to prevent invasive meningococcal disease caused by serogroup B (also known as meningitis B) in adolescents and young adults from 10 years through 25 years of age. Bexsero is the only meningitis B vaccine approved in the US with a two-dose regimen and a flexible dosing schedule<sup>1</sup>. As part of the accelerated approval process, Novartis will complete its ongoing studies to confirm the effectiveness of Bexsero against diverse serogroup B strains.

"While rare, meningitis B is a devastating disease that can hit anyone anytime, especially teenagers and children," said Andrin Oswald, Division Head, Novartis Vaccines. "This approval is an important milestone towards our goal of helping to prevent any further loss of life."

In Phase II and Phase III studies, Bexsero demonstrated a protective immune response in adolescents and young adults after two doses. Bexsero also offers a flexible dosing schedule, with the first and second doses administered at least one month apart<sup>1</sup>.

"As someone who contracted meningitis during college, I am hopeful that young adults across the country will soon have routine access to meningitis B vaccines," said Jamie Schanbaum, 25-year-old founder of the meningitis advocacy organization The J.A.M.I.E. Group. "There is no reason that young people in the US should be in danger of a vaccine-preventable disease as devastating as meningitis."

The tolerability profile of Bexsero was also demonstrated as part of a US Centers for Disease Control and Prevention (CDC)-sponsored clinical trial conducted in more than 15,000 individuals at Princeton University and the University of California, Santa Barbara (UCSB) during meningitis B outbreaks on these college campuses. The safety data from the CDC clinical trial are consistent with results observed in previous studies<sup>1,4</sup>.

Invasive meningococcal disease, which may present as bacterial meningitis, can be easily misdiagnosed and while rare, it can have serious consequences including lifelong disability and sometimes death within 24 hours of symptom onset<sup>2,3</sup>. *Neisseria meningitidis* B has become the most prevalent of the serogroups that cause meningococcal disease in the US, accounting for 33 percent of all reported cases in

2013<sup>5</sup>. Even with antibiotic treatment, as many as 10 percent of people infected with meningococcal disease will die and almost one in five survivors will suffer long-term disability<sup>2</sup>. Adolescents and young adults are at an increased risk of contracting meningococcal disease due to common lifestyle habits, such as living in college dormitories<sup>2</sup>.

In January 2013, Bexsero was approved by the European Commission for use in individuals from 2 months of age and older, making it the first broad coverage vaccine to receive a regulatory approval to help protect against meningitis B. The US approval of Bexsero underscores the unique leadership position of Novartis in the global fight against meningococcal disease. Together, Bexsero and Menveo<sup>®</sup> (Meningococcal Group A, C, W-135 and Y conjugate vaccine) help to protect against all five main serogroups of meningococcal bacteria (A, C, W-135, Y and now B) that cause the majority of cases in the US and around the world<sup>1,3</sup>.

### **About Bexsero**

Bexsero is now licensed in 37 countries including the member states of the European Union, Australia and Canada for use in individuals from 2 months of age and older. Since being first approved in Europe, over 1 million doses of the vaccine have been distributed outside the US. In the US, it is approved for use in adolescents and young adults from 10 years through 25 years of age<sup>1</sup>. Last year, health officials in Canada released the initial results of a large-scale vaccination campaign with the Bexsero to help protect against meningococcal serogroup B within the Saguenay-Lac-Saint-Jean region of Quebec, Canada. The regional program is the first of its kind globally and has reached 81 percent of the campaign's target population within the first three months. This encompasses more than 45,000 infants, young children and adolescents from 2 months to 20 years of age. The interim safety surveillance report showed that Bexsero has been generally well tolerated, consistent with data found in clinical trials<sup>6</sup>.

For more information about Bexsero, visit [www.bexsero-us.com](http://www.bexsero-us.com).

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by words such as "may," "will," "goal," "hopeful," "soon," "can," or similar terms, or by express or implied discussions regarding potential additional marketing approvals for Bexsero and Menveo, or regarding potential future revenues from Bexsero and Menveo. 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 either Bexsero or Menveo will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Bexsero or Menveo will be commercially successful in the future. In particular, management's expectations regarding Bexsero and Menveo could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; 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 over-the-counter 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 130,000 full-time-equivalent associates and sell products in more than 150 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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