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Novartis meningitis B vaccine Bexsero® receives FDA Breakthrough Therapy designation in the US

- The designation highlights the potential of Bexsero to meet the urgent need for a licensed vaccine in the US against unpredictable and devastating meningitis B¹

- Bexsero, already approved in Europe, Canada and Australia, is the only broad coverage meningitis B vaccine that can be used from two months of age³,⁴,⁵

- Bexsero was recently provided to two US universities under an Investigational New Drug (IND) designation; Novartis plans to file in the US as early as Q2 2014⁶,⁷

Basel, April 7, 2014 – Novartis announced today that Bexsero® (Meningococcal Group B Vaccine [rDNA, component, adsorbed]) has received a Breakthrough Therapy designation from the United States Food and Drug Administration (FDA). Bexsero is already approved in Europe, Canada and Australia to help protect against invasive meningococcal disease caused by serogroup B (meningitis B)²,³,⁴,⁵. Novartis plans to file for US licensure of Bexsero as early as Q2 2014; exact timing will depend on guidance from the FDA. This is the fourth Breakthrough Therapy designation for Novartis, underscoring leadership in developing innovative therapies and vaccines⁶,⁹,¹⁰.

This announcement comes on the heels of a landmark decision from regulators in the UK, where the Joint Committee on Vaccination and Immunisation (JCVI) recommended the inclusion of Bexsero in the country’s National Immunisation Programme (NIP) for routine use in infants from two months of age¹¹.

In the last four months, Novartis has provided nearly 30,000 doses of Bexsero to students and staff at Princeton University and the University of California Santa Barbara (UCSB) following meningitis B outbreaks on their campuses under an Investigational New Drug (IND) designation from the FDA⁶,⁷,¹². Further, the US Centers for Disease Control and Prevention (CDC) have recommended including the incoming freshman class at Princeton University in the at-risk group to receive Bexsero.

“The recent outbreaks on US university campuses have shown that meningitis B is unpredictable and can strike at any time with devastating consequences,” said Andrin Oswald, Division Head, Novartis Vaccines. “A US license for Bexsero is the only sustainable solution to ensure timely responses to future outbreaks and to provide access to parents and physicians across the country. We will continue to work with the FDA to bring Bexsero to the US as soon as possible.”

According to the FDA, Breakthrough Therapy designation is intended to expedite the development and review of new medicines that treat serious or life-threatening conditions. The designation includes all of the fast track program features, as well as more intensive FDA guidance¹³. Meningitis B is the leading cause of bacterial meningitis and septicemia in the developed world¹⁴. With vaccines currently available in the US to help prevent the other four most common serogroups that cause meningococcal disease...
(A, C, Y and W), a licensed vaccine offering protection against serogroup B remains an unmet public health need in the US. Today’s announcement also highlights Novartis’ leadership in developing innovative vaccines against meningococcal disease, as the only company with licensed vaccines for all five main serogroups that together cause the majority of cases in the world.

Meningitis B is a rare but aggressive disease that can kill or cause serious life-long disability within 24 hours of onset. Because initial symptoms are often unspecific and flu-like, it can be difficult for even a healthcare professional to diagnose the disease in its early stages. About one in 10 of those with the disease will die despite appropriate treatment and of those who do survive, one in five will suffer from devastating, life-long disabilities such as brain damage, hearing loss or limb loss. Vaccination is therefore the best defense against the disease which leaves little time for intervention.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “Breakthrough Therapy,” “potential,” “unpredictable,” “plans,” “will,” “recommended,” “can,” or similar terms, or by express or implied discussions regarding potential marketing authorizations for Bexsero, or regarding potential future revenues from Bexsero and other Novartis vaccines. 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 in any additional markets, or at any particular time. Nor can there be any guarantee that Bexsero or such other Novartis vaccines will be commercially successful in the future. In particular, management’s expectations regarding Bexsero and such other Novartis vaccines 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; 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.

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