Bexsero®: Targeting Meningococcal Group B

- Bexsero® (Meningococcal Group B Vaccine) is approved in the US for active immunization to help prevent invasive meningococcal disease caused by Neisseria meningitidis group B in adolescents and young adults from 10 years through 25 years of age.
- Bexsero is administered in a two-dose series at least one month apart, which may allow patients to complete the series in a summer.
- Bexsero is now licensed in 37 countries; since first approval in Europe, over 1 million doses shipped worldwide.
- Phase III clinical data in adolescents showed Bexsero generated a protective immune response after two doses.

About Bexsero

In January 2015, Bexsero® was approved by the US Food & Drug Administration (FDA) for active immunization to help prevent invasive meningococcal disease caused by Neisseria meningitidis group B in adolescents and young adults from 10 years through 25 years of age. The effectiveness of Bexsero against diverse group B strains has not been confirmed.

Outside of the US, Bexsero is currently licensed in 36 countries including the European Union, Australia and Canada for use in individuals from 2 months of age and older.

Clinical data and experience in other countries where the vaccine is approved reinforce the positive attributes of Bexsero

- In two Phase III studies, Bexsero demonstrated a protective immune response in adolescents and young adults after two doses (doses administered at least one month apart).
- The US approval of Bexsero was based on safety studies using 3,058 patients.

In response to outbreaks of meningococcal group B disease at Princeton University and the University of California-Santa Barbara (UCSB), Bexsero was administered as a two-dose series at least one month apart, as part of a clinical trial initiated by US Centers for Disease Control and Prevention (CDC) under an Investigational New Drug (IND) application. Information on serious adverse events was collected for a period of 30 days after each dose from 15,351 individuals who received at least one dose. Overall, 50 individuals (0.3%) reported serious adverse events, which is consistent with results observed in previous studies.

Bexsero – Meningococcal Group B Vaccine

Bexsero is the result of more than 20 years of pioneering research in vaccine development. Bexsero was developed using an award-winning scientific approach that involved decoding the genetic makeup (genome sequence) of Neisseria meningitidis group B. This innovative approach provides the foundation for a new generation of vaccines that can help prevent other diseases with a significant diversity of disease-causing strains.

Novartis is committed to providing successful vaccines to help globally protect against the five main groups of meningococcal bacteria (A, B, C, W-135 and Y). The US approval of Bexsero underscores the unique leadership position of Novartis in the global fight against this devastating disease. Bexsero and Menveo® (Meningococcal Group A, C, W-135 and Y conjugate vaccine) help to protect against the five main groups of meningococcal bacteria that cause
the majority of cases across the globe\textsuperscript{3,4}. In the US, the most prevalent groups are B, C and Y\textsuperscript{1}.

**Meningococcal Group B – A cause of devastating disease**

Invasive meningococcal disease, which may present as bacterial meningitis and while rare, can have serious consequences including lifelong disability and sometimes death within 24 hours of symptom onset\textsuperscript{5,6,7}. *Neisseria meningitidis* group B has become one of the most prevalent groups that cause meningococcal disease in the US, accounting for 33 percent of all reported cases in 2013\textsuperscript{8}. Even with appropriate treatment, as many as 10 percent of people with meningococcal disease will die and almost one in five survivors will suffer long-term disability\textsuperscript{7,9,10}. Adolescents and young adults are at risk of contracting meningococcal disease due to social factors, such as kissing and living in college dormitories\textsuperscript{3,11}.

**References**

1. Bexsero Prescribing Information.
4. Menvueo Prescribing Information.