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Novartis receives positive CHMP opinion for Bexsero®, a groundbreaking vaccine to help prevent devastating MenB infections, the leading cause of meningitis in Europe

- Meningococcal serogroup B (MenB) disease is easily misdiagnosed, can kill within 24 hours and may cause serious, life-long disabilities.¹,²
- Upon approval, Bexsero will be the first and only broad coverage MenB vaccine to help protect all age groups, including infants
- Anticipated approval of Bexsero highlights Novartis leadership position in global fight against meningococcal disease

Basel, November 16, 2012 – Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for Bexsero (Meningococcal Group B Vaccine [rDNA, component, adsorbed]) for use in individuals from 2 months of age and older. Upon regulatory approval, Bexsero will be the first licensed broad coverage vaccine that can help protect all age groups against MenB disease,³ including infants, the age group at the greatest risk of infection.⁴

“We are proud of the major advance that Bexsero represents within the field of vaccine development against what up until now has been a very challenging disease target,” said Andrin Oswald, Division Head, Novartis Vaccines and Diagnostics. “For over two decades, our researchers and clinicians have been dedicated to finding a solution to prevent MenB disease. Our steadfast determination has been inspired by the testimonies from survivors and families who have lost loved ones to this disease.”

Currently available vaccines do not offer broad protection against MenB, which accounts for up to 90% of all meningococcal disease cases in some European countries.⁵ MenB disease is easily misdiagnosed, can kill within 24 hours and may cause serious, life-long disabilities.¹,² About 1 in 10 of those who contract the disease dies despite appropriate treatment.² Up to one in five survivors suffers from devastating, life-long disabilities such as brain damage, hearing impairment or limb loss.⁵ The highest rates of MenB disease occur in the first year of life, peaking by 7 months of age.⁶

“MenB disease is a major cause of meningitis and septicemia in children, and its ability to cause a rapidly progressive, devastating illness makes it one of the infections most feared by both parents and pediatricians,” said Dr Matthew Snape, Consultant in Pediatrics and Vaccinology at the Oxford Vaccine Group, University of Oxford. “A vaccine that is able to reduce the incidence of this disease would be a major advance towards the prevention of childhood meningitis.”

The European Commission generally follows the recommendations of the CHMP and delivers its final decision within three months, which will be applicable to all European Union (EU) and European Economic Area (EEA) countries. Upon approval, each member state will evaluate Bexsero reimbursement schemes and determine the potential
inclusion of the vaccine into National Immunization Programs. Novartis is committed to making Bexsero available as soon as possible and is already engaging with governments interested in the early adoption of the vaccine.

The tolerability profile and immunogenicity of Bexsero has been established through a comprehensive clinical program including data from large Phase II/III clinical trials involving almost 8,000 infants, children, adolescents and adults.\(^7,8,10,11,12\) Starting from two months of age, Bexsero offers several immunization schedule options that can fit with routine vaccination visits.

“We welcome this news, which is immensely significant for parents and doctors. For the first time in the fight against meningococcal disease, we have in sight a potential solution in protecting against MenB disease,” said Bruce Langoulant, President and Member, Governing Council of Confederation of Meningitis Organisations (CoMO), and father of a meningitis survivor. “Many of our members and supporters have been personally impacted by meningitis and have watched as loved ones suffered the devastating effects of this disease.”

Bexsero is the result of more than 20 years of pioneering vaccine research.\(^13\) MenB has been a particularly challenging target because the outer coating of the bacteria is not well recognized as an antigen by the immune system, making it especially difficult to develop a broadly effective vaccine until recent scientific developments.\(^14\) Bexsero was developed using an award-winning scientific approach that involved decoding the genetic makeup (genome sequence) of MenB.\(^14,15\) 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.

Following the approval of Menveo\(^\circ\) in 2010, the anticipated approval of the groundbreaking vaccine Bexsero underscores the unique leadership position of Novartis in the global fight against devastating meningococcal disease. Together, the two vaccines help to protect against all five main serogroups of meningococcal bacteria (A, B, C, W-135 and Y) that cause the majority of cases around the world.\(^15\)

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