

Health Canada Approves Bexsero*, the First Vaccine Available to Prevent Meningococcal Serogroup B (MenB) ^{1,2}

- *Bexsero* is indicated to help protect individuals from two months through 17 years of age against meningococcal B disease, including infants, children one to four years and adolescents who are at the greatest risk of infection^{2,3}*
- *MenB is the most common type of meningitis in Canada⁴. It is responsible for 80 per cent of meningococcal cases in infants under one year of age, 67 per cent in one to four year olds and 62 per cent of the cases in adolescents aged 15 to 19³*
- *MenB invasive meningococcal infections cause substantial morbidity and mortality and are the leading cause of invasive meningococcal disease in Canada⁴*

Dorval, December 9 2013 – Novartis announced today that Health Canada has approved Bexsero* (Multicomponent Meningococcal B Vaccine [recombinant, adsorbed]) for use in individuals from two months through 17 years of age². Bexsero* is the first broad coverage vaccine to help protect against meningococcal serogroup B (MenB) disease, including infants, toddlers and adolescents who are at the greatest risk of infection^{1,2,3}.

MenB infection is the leading cause of meningococcal disease across Canada, particularly in infants^{3,4}. Although rare, this disease is feared as it affects healthy people rapidly and without warning^{5,6}. Meningococcal disease can cause significant mortality in 24 - 48 hours and early symptoms can often resemble the flu, making this disease initially misdiagnosed in its early stages⁵.

“Until now, we have had no vaccine against MenB that could be used routinely to protect infants, children, teens against this devastating disease,” said Dr. Ron Gold, Senior Medical Advisor of the Meningitis Research Foundation of Canada and retired Chief of Infectious Disease at The Hospital for Sick Children in Toronto. “The MenB vaccine is designed to reduce the risk of disease in those most at risk and provide parents with peace of mind. The new MenB vaccine has the potential to fill the last remaining gap in vaccines to prevent all of the major causes of bacterial meningitis outside of the newborn period. I encourage parents to talk to their doctor about meningitis and how they can protect their children with vaccines. I also hope that the new MenB vaccine will rapidly be added to the routine immunization programs throughout Canada.”



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About 10 per cent to 14 per cent of people who contract the disease will die despite appropriate treatment⁵. Up to 20 per cent of survivors may suffer from devastating, life-long disabilities such as neurological disabilities, hearing loss or limb loss⁵. Prevention through vaccination is considered the best control strategy against an aggressive disease that leaves little time for intervention⁵.

Novartis is dedicated to providing healthcare solutions that address the evolving needs of patients and societies. Novartis is working with health authorities to provide access to Bexsero* as soon as possible.

Meningococcal disease is caused by *Neisseria meningitidis*⁵. Five main groups of meningococcal bacteria (A, B, C, W and Y) cause virtually all cases around the world⁵. Prior to Bexsero*, vaccines were available to help protect only against A, C, W and Y strains⁶.

About Bexsero*

Bexsero* is the result of more than 40 years of pioneering vaccine research and its tolerability profile and immunogenicity have been established through a comprehensive clinical program involving infants, children, adolescents and adults^{2,7}.

Bexsero* is the first broad coverage meningococcal MenB vaccine to demonstrate an immune response in infants, for use in individuals from two months through 17 years of age, the population at greatest risk for developing this devastating disease^{1,2,3}. Bexsero* provides a flexible option that can fit into various vaccination schedules^{8,9}. When given with other childhood vaccinations there is little impact on immunogenicity of Bexsero* or the other vaccines^{8,9}.

The approval of Bexsero* underscores the unique leadership position of Novartis in the global fight against devastating meningococcal disease. Together, Bexsero* and Menveo* help to protect against all five main serogroups of meningococcal bacteria (A, C, W, Y and now B) that cause virtually all cases around the world⁶.

Bexsero* will be available for sale in early 2014.

About Novartis Inc.

Novartis Pharmaceuticals Canada Inc., a leader in the healthcare field, is committed to the discovery, development and marketing of innovative products to improve the well-being of all Canadians. In 2012, the company invested close to \$100 million in research and development in Canada. Novartis Pharmaceuticals Canada Inc. employs more than 600 people in Canada. For further information, please consult www.novartis.ca.



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* *Bexsero and Menveo are registered trademarks.*

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¹ Novartis Bexsero EU Approval Press Release. Available at: <http://www.novartis.com/newsroom/media-releases/en/2013/1672036.shtml>. Accessed November 2013.

² BEXSERO* Product Monograph. Novartis Pharmaceuticals Canada Inc., December, 2013

³ National Advisory Committee on Immunization. (2013) Update on the use of Quadrivalent Conjugate Meningococcal Vaccines. Canada Communicable Disease Report. January 2013; Vol. 39, ACS-1: 1-40.

⁴ Bettinger ,J et al. for IMPACT. The Disease Burden of Invasive Meningococcal Serogroup B Disease in Canada. The Pediatric Infectious Disease Journal, January 2013; Vol. 32 (1) e20-e25.

⁵ Harrison LH. Prospects for vaccine prevention of meningococcal infection. Clin Microbiol Rev. 2006; 19(1):142-1643. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1360272/pdf/002>.

⁶ Perrett KP, Pollard AJ. Towards an improved serogroup B Neisseria meningitidis vaccine. Expert Opin Biol Ther. 2005;5:1611-1625. Available at: <http://informahealthcare.com/doi/abs/10.1517/14712598.5.12.1611>. Accessed on August 24, 2013

⁷ Rappuoli, R. Reverse vaccinology, a genome-based approach to vaccine development. Vaccine. 2001; 19: 2688–2691. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/11257410>.

⁸ Gossger N et al. (2012) Immunogenicity of recombinant serogroup B meningococcal vaccine administered with or without routine infant vaccinations according to different immunization schedules: a randomized controlled trial. JAMA 307(6):573-82.



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⁹ Vesikari, T et al., Immunogenicity and safety of an investigational multicomponent, recombinant, meningococcal serogroup B vaccine (4CMenB) administered concomitantly with routine infant and child vaccinations: results of two randomised trials. *Lancet*, 2012; Vol 381. Available at: [http://dx.doi.org/10.1016/S0140-6736\(12\)61961-8](http://dx.doi.org/10.1016/S0140-6736(12)61961-8)