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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 Canada[4]. 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 19[3]*

- *MenB invasive meningococcal infections cause substantial morbidity and mortality and are the leading cause of invasive meningococcal disease in Canada[4]*

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 age[2]. 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 stages[5].

“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 treatment[5]. Up to 20 per cent of survivors may suffer from devastating, life-long disabilities such as neurological disabilities, hearing loss or limb loss[5]. Prevention through vaccination is considered the best control strategy against an aggressive disease that leaves little time for intervention[5].

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 world[5]. Prior to Bexsero*, vaccines were available to help protect only against A, C, W and Y strains[6].

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 world[6].

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

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Canada. Novartis Pharmaceuticals Canada Inc. employs more than 600 people in Canada. For further information, please consult www.novartis.ca.

Novartis Pharmaceuticals Canada Inc. is an affiliate of Novartis AG, which 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 diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 129,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

** Bexsero and Menveo are registered trademarks.*

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