

Novartis MenB vaccine gets approval in Australia

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Singapore: Australian Therapeutic Goods Administration (TGA) has approved Novartis' Bexsero, a multi-component Meningococcal B (MenB) vaccine (recombinant, adsorbed) suspension for injection 0.5 ml pre-filled syringe, to the Australian Register of Therapeutic Goods (ARTG) for use in individuals from two months of age and older. Bexsero is the first and only broad coverage vaccine to help protect all age groups against MenB disease, including infants who are at the greatest risk of infection.

Across Australia, approximately 85 percent of all meningococcal disease and sepsis cases have been caused by MenB, a percentage that has risen in recent years as the number of cases in other serogroups has fallen. The introduction of vaccines for other strains of bacterial meningitis has been successful in reducing the disease burden in Australia; specifically, following the rollout of a national meningococcal serogroup C vaccination program in Australia, cases decreased from 162 in 2002 to nine by 2011.

"Novartis welcomes the Australian health authorities' decision to license Bexsero, which is further testament to the vaccine's demonstrated robust efficacy and safety profiles and an important step in preventing further suffering caused by MenB disease," said Dr Andrin Oswald, Division Head, Novartis Vaccines and Diagnostics. "We are committed to bringing Bexsero to parents around the globe that want to protect their children against this devastating disease."

MenB is a potentially deadly disease which is easily misdiagnosed and can kill within 24 hours of onset. About one in 10 of those who contract the disease will die despite appropriate treatment. Up to one in five survivors may suffer from devastating, life-long disabilities such as brain damage, hearing impairment or limb loss. The consequences for those affected and the healthcare system are significant.

"Today marks another victory, particularly for Australian children, parents and pediatricians, in the fight against meningococcal disease," said Mr Bruce Langoulant, president and Asia Pacific regional leader, Confederation of Meningitis Organizations. "We are now entering a critical period for public health authorities to provide funding to include the new MenB vaccine in the routine immunization schedules to ensure community-wide protection against the tragic deaths and lasting disabilities MenB can cause."

As a next step, Novartis will work with Australian regulatory authorities to make doses of Bexsero available in the private

market in the coming months. In parallel, the Pharmaceutical Benefits Advisory Committee (PBAC), taking into account advice from the Australian Technical Advisory Group on Immunisation (ATAGI), is expected to make recommendations regarding reimbursement and potential inclusion of Bexsero in the National Immunisation Program.