‘Real world’ data shows 83 percent effectiveness for Bexsero® in infants in first year of UK national meningitis B immunisation programme

Monday 5 September, 2016

Preliminary data from the world’s first national meningitis B immunisation programme with Bexsero1, launched one year ago in the UK, shows the estimated effectiveness of the vaccine at 83 percent against any meningitis B strain and 94 percent against vaccine preventable strains, for all children receiving the first two of three recommended doses 2. Reported cases of the disease have dropped 50 percent in the vaccine-eligible population in the first ten months of the programme, compared to the average number of cases over the last four years. These data were presented today by Public Health England (PHE) at the International Pathogenic Neisseria Conference (IPNC) in Manchester, UK.

Uptake of the vaccine in the UK national immunisation programme is high. In more than 600,000 infants aged 0-1 year old, eligible for the vaccine, more than 90 percent received two doses.

Dr. Thomas Breuer, Chief Medical Officer, GSK Vaccines commented: “We are extremely encouraged by the initial results of the UK programme, which demonstrate that Bexsero helps to protect babies in the UK from this often life-threatening disease. The data substantially advance our understanding of the impact of meningitis B vaccines in a real world setting and may help inform public health authorities around the world about their future use. The report shared provides reassurance to parents who have already vaccinated their children or wish to help protect their children from meningitis B in the future.”

Invasive meningococcal B disease is the leading cause of life-threatening meningitis in the industrialised world. Although not common, invasive meningococcal B disease develops rapidly, typically amongst previously healthy children and adolescents, and results in high morbidity and mortality. Initial symptoms can often resemble flu, making it difficult to diagnose. About one in 10 of those who contract the disease will die, even with appropriate treatment. Additionally, up to 20 percent of those who survive bacterial meningitis may suffer a major physical or neurological disability (limb loss, hearing loss or seizures).3,4

Bexsaro is currently the only meningococcal B vaccine licenced in Europe. The UK national immunization programme is the first such programme for the prevention of menigitis B in the world. Bexsaro is currently the only meningococcal B vaccine licenced in Europe. The UK national immunization programme is the first such programme for the prevention of menigitis B in the world. Bexsaro is currently the only meningococcal B vaccine licenced in Europe. The UK national immunization programme is the first such programme for the prevention of menigitis B in the world.Bexsero is currently the only meningococcal B vaccine licensed in Europe. The UK national immunisation programme is the first such programme for the prevention of meningitis B in the world. Infants are immunised at two and four months of age, with a booster dose at 12 months, outside of the licensed dosing schedule*, but in line with recommendations issued by the UK advisory body on immunisation2. The data presented today demonstrate the immediate impact on meningococcal B disease rates in the eligible population following two doses of the vaccine. More data are expected as the first infants from the programme receive their booster dose later this year.

Linda Glennie, head of research at the Meningitis Research Foundation said, “It is great to see this early evidence that the national meningitis B immunisation programme for children under age one is effective. We hope that other countries burdened by meningitis B will now consider protecting their people from this deadly disease. Meningitis and septicaemia can kill in hours, and leave a substantial number of survivors with life-changing after-effects. We will continue to gather evidence that will unlock expertise about meningitis B vaccination.”

Incidence of meningitis B is highest in infants under one year old and the ultimate goal of meningococcal vaccination is to reduce the total burden of disease. The data presented today at IPNC shows this is now happening in the UK. GSK looks forward to further analyses from PHE on the vaccine’s effectiveness over the coming months and years.

Notes to Editors

Bexsero®? [Meningococcal group B Vaccine (rDNA, component, adsorbed)]

Bexsero is licensed in more than 35 countries5, including the U.S. These countries include the member states of the European Union and European Economic Area, Australia, Argentina, Chile and Uruguay, where Bexsero is approved for individuals two months of age and older, and in Canada for those aged 2

months to 17 years of age. In the U.S., Bexsero is approved for use in individuals from 10 years through 25 years of age. In Brazil, Bexsero is approved for use in individuals from two months to 50 years of age.

Refer to SPC for adverse events and safety guidance.

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Cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2015.

References

1 Bexsero Summary of Product Characteristics https://www.medicines.org.uk/emc/medicine/28407

2 In line with the recommendations made by the Joint Committee on Vaccination and Immunisation, (JCVI). JCVI position statement on use of Bexsero® meningococcal B vaccine in the UK. March 2014.

3 WHO factsheet: http://www.who.int/mediacentre/factsheets/fs141/en/

4 Viner RM, et al. Lancet Neurol. 2012;11:774-783

5 Watson PS, Turner DPJ. Clinical experience with the meningococcal B vaccine, Bexsero®: Prospects for reducing the burden of meningococcal serogroup B disease. Vaccine 34 (2016) 875–880 http://dx.doi.org/10.1016/j.vaccine.2015.11.057

*SPC :

Last accessed September 2016

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