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SAFETY PROFILE OF MENVEO® IN ADOLESCENTS AND ADULTS ENROLLED IN PHASE III CLINICAL TRIALS

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Background: Safety information about Menveo,® a novel quadrivalent meningococcal conjugate vaccine against serogroups A, C, W-135 and Y, was collected during the clinical development program. An integrated summary of safety data has not been previously presented.

Methods: Five randomized controlled studies that shared similar inclusion/exclusion criteria and safety and tolerability endpoints were evaluated to provide a clinical picture of the safety of Menveo, which was then compared with that of two previously licensed vaccines (Menactra® and Menomune®) in the context of sequential or co-administration with licensed routine adolescent vaccines (Tdap and HPV). Solicited injection site and systemic reactions were recorded for 7 days postvaccination; adverse events were monitored for at least six months after vaccination.

Results: A total of 6752 adolescents and adults enrolled in clinical trials and received study vaccines at clinical centers in the United States, Italy, and Latin America. Similar patterns of solicited reactions were observed in Menveo® and comparator meningococcal vaccine recipients. Safety results were consistent for Menveo® whether it was administered concomitantly or sequentially with Tdap and HPV without evidence of enhanced local reactogenicity. No consistent, unanticipated patterns were observed in adverse event profiles in the any of the clinical trials. As anticipated, serious adverse events were rare in these participants.

Conclusion: In a database of several thousand adolescents and adults, Menveo® was generally well tolerated without evidence of increased reactogenicity or clinically significant patterns of medical consequence when co-administered with recommended adolescent vaccines.

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ROTAVIRUS VACCINE EFFECTIVENESS IN SPAIN

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Background and aims: Current rotavirus vaccines have showed outstanding effectiveness in USA, but data coming from Europe are still scarce. Effectiveness of rotavirus vaccination in Spain - where both rotavirus vaccines are available since 2007- has been estimated.

Methods: A prospective observational study was conducted from Oct-2008 through Jun-2009 including 682 children up to 5 years-old with AGE attended in primary care (n=18 centres), and ER and hospital settings (n=10 centres), covering Galicia and Asturias regions (North-West Spain). A rapid stool immunochromotagographic test for rotavirus antigen detection (test VIKIA, BioMerieux) was at least performed in all included patients. Rotavirus vaccine global effectiveness was estimated as 1-OR after comparing the frequency of rotavirus vaccination in patients positive and negative to rotavirus etiology. Rotavirus vaccine effectiveness (RVVE) to prevent hospital admission was also calculated.

Results: Of 682 enrolled children, 207(30.4%) were rotavirus positive and 152(22%) had received at least one dose of rotavirus vaccine. In 163 patients (24%) hospital admission was required, but patients with rotavirus AGE were admitted to hospital more frequently (47.8%vs14%)[p< .001]. RRVE (after at least one vaccine dose) to prevent rotavirus AGE was 90.5%(95%confidence interval: 82%-95%). RVVE to prevent hospital admission due to rotavirus AGE was 94.7%(83-98.4%). Once a child has an AGE, being vaccinated reduced the risk of admission by 44% with a number needed to vaccinate of 4 (p values were non significant).

Conclusions: Rotavirus vaccines have also showed an outstanding effectiveness in Spain despite low-medium coverage rates yet.