(1) Submission ID#1536820

Single Center, Randomized, Observer-blinded, Active Comparator Phase I Study to Assess the Safety and Immunogenicity of Meningococcal (Groups A, C, W-135, X and Y) Conjugate Vaccine in Healthy Adults

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Background

Meningococcus (Neisseria meningitidis) is a major causative agent of septicemia and meningitis in children and adults. Despite adequate therapy, estimated mortality is high (10%) and a portion (15%) of individuals have residual neurologic damage. There are no licensed vaccines for meningococcal conjugate vaccines containing serogroup X that the incidence of which has been on the rise along the African meningitis belt in the past 10 years. EuNmCV-5 developed by EuBiologics Co., Ltd. is a pentavalent meningococcal conjugate vaccine including the serogroups of meningococcal groups A, C, W-135, X, and Y, and it is a meningococcal-rCRM197 conjugate vaccine containing recombinant-CRM197 (rCRM197), an immune-enhancing carrier protein. The safety and efficacy of the EuNmCV-5 in Phase 1 study is currently underway in Republic of Korea, and a Phase 2/3 study in Africa is planned.

Aim/Methods

To evaluate safety and immunogenicity after administration of EuNmCV-5 in healthy adults, Phase 1 (ClinicalTrials.gov Identifier: NCT05739292); the first in human clinical study, by comparing with MENVEO® in Republic of Korea. This study includes a total of 60 healthy adults (≥ 19and≤55 years old) and was designed as a single institution, randomized, observer blinded, clinical trial with an active comparator (MENVEO®). After eligibility screening, participants are randomized (1:1 ratio) to receive a single dose of the investigational product or MENVEO®. The primary endpoint is safety and tolerability. Immediate adverse events (related to anaphylaxis) are observed for 30 minutes after administration of investigational product, and safety is evaluated at 28 days and up to 180 days after dosing. Immunogenicity evaluation is conducted at 28 days after dosing, and seroresponse rate (rSBA titer increases from < 1:8 to ≥ 1:32, more than 4 times, ≥ 1:8 or ≥ 1:128) and rSBA GMT are evaluated.

Results

Pending. Phase I study enrolment was completed on April 6th 2023. To date (3May2023), there were no serious adverse events. Day 28 safety and immunogenicity data are expected within August 2023. Phase 2/3 studies are under development and are expected to commence in West Africa in March 2024.

Conclusions

With success, EuNmCV-5 will be a pentavalent meningococcal vaccine with the additional benefit of protection against serogroup X.