U.S. FOOD & DRUG ADMINISTRATION

FACTOR H BINDING PROTEIN-CHOLERATOXIN B CHIMERIC VACCINE CONSTRUCT AGAINST NEISSERIA MENINGOCCAL DISEASE

Technology Summary

The predominant cause of meningitis or the inflammation of the membrane that lines the brain and spinal cord, is by the bacterium *Neisseria meningitidis* (*N. meningitidis*). Though outbreaks of this disease are rare, meningitis is associated with a high fatality rate (50% untreated) and a high frequency of long-term symptoms (10-20%). There are 2 types of meningococcal vaccines available in the United States: MenACWY vaccines (Menactra® and Menveo®) and MenB vaccines (Bexsero® and Trumenba®).

The *N. meningitidis* factor H binding protein (FHbp) is an important virulence factor and vaccine antigen that is used in both licensed serogroup B meningococcal vaccines. Recent studies in human factor H (hFH) transgenic mice suggest that hFH-FHbp interactions lower FHbp-elicited immunogenicity. To characterize and potentially improve FHbp immunogenicity, FDA investigators have developed an FHbp-cholera holotoxin-like chimera vaccine expression system in Escherichia coli that utilizes cholera toxin B (CTB) as both a scaffold and adjuvant for FHbp. Any combination of the *N. meningitidis* capsular polysaccharide serogroups (A, B, C, D, X, Y, Z, 29E, and W) can be conjugated to the fHbp-CTB scaffold. In studies, the chimeras induced significantly more immunogenic effect than FHbp alone or mixed with CTB, eliciting bactericidal antibodies against a panel of meningitis B isolates.

Potential Commercial Applications

- Vaccine development for group *N. meningitidis* serogroup B strains

Competitive Advantages

- Vaccine platform
- No need for protein lipidation or exogenous adjuvants
- Any combination of the *N. meningitidis* capsular polysaccharide serogroups (A, B, C, D, X, Y, Z, 29E, and W) can be conjugated to the fHbp-CTB scaffold

Development Stage: Early Proof of concept studies completed

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Intellectual Property: US Patent Application No. 16/954,161 filed 6/15/2020

Publications:

- Price, AP. and Bash, MC. Development of an FHbp-CTB holotoxin-like chimera and the elicitation of bactericidal antibodies against serogroup B Neisseria meningitidis. Vaccine. 2018 Jan 29;36(5):644-652. PMID: 29287682

Product Area: vaccine development, adjuvant,

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