BioMARC Awarded Typhoid Vaccine Manufacturing Project for Boston Children's Hospital

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BioMARC, the Biopharmaceutical Manufacturing and Academic Resource Center, a non-profit biologics contract development and manufacturing organization (CDMO), owned and operated by Colorado State University (CSU), has been awarded a new contract with Boston Children's Hospital (BCH). BCH is the world's largest research enterprise based at a pediatric hospital and is affiliated with Harvard Medical School. The contract is for the scale-up and manufacturing process development for an innovative vaccine candidate for *Salmonella typhi* and *Salmonella paratyphi*, incorporating the groundbreaking Multiple Antigen Presenting System (MAPS) vaccine platform developed by Dr. Fan Zhang, Instructor of Pediatrics at Harvard Medical School, Dr. Yingjie Lu, Assistant Professor of Pediatrics at Harvard Medical School, and Dr. Richard Malley, Senior Physician in Medicine at Boston Children's Hospital and Professor of Pediatrics at Harvard Medical School.

Salmonella typhi infection (often called typhoid fever) is a major cause of morbidity and mortality worldwide, and current vaccines are not suitable for young children. *Salmonella paratyphi* infection has emerged as an important cause of enteric disease in Asia with no available vaccine. Initial pre-clinical studies with the MAPS-based vaccine candidate have demonstrated a potent immune system response. The Bill & Melinda Gates Foundation has funded the Boston Children's Hospital program to further develop their novel vaccine platform to address this significant global health threat.

BioMARC will manufacture the bulk drug substance, formulate and fill-finish the drug product into vials. Other project aspects include analytical method technical transfer as well as release and stability testing of the finished drug product. The work will be conducted under phase-appropriate conditions and the resulting drug product may be used for pre-clinical toxicology studies, inactivation validation studies, or similar studies which are crucial to the development process for a human vaccine candidate. "This project is a great fit for BioMARC's expertise," noted BioMARC Director Dr. John Wyckoff. "When creative scientists perform research that leads to promising drug candidates, at some point they need to transition from an academic laboratory setting into a regulated manufacturing environment and scale-up their processes. This often presents new sets of challenges that need to be addressed. BioMARC's experienced technical and regulatory team are excited to work on this new vaccine platform and to help get this much needed vaccine further down the development pathway."

About BioMARC

BioMARC is a not-for-profit biologics CDMO, owned and operated by CSU, serving biopharma companies and government agencies. BioMARC specializes in high containment to safely handle BSL-2 and BSL-3, CDC Tier 1 select agents, and spore-forming microorganisms. Development and manufacturing are performed under phase-appropriate GLP or cGMP conditions for production of pre-clinical, clinical and commercial biologics products. Services include process and method development, cell, bacteria, and virus banking, bulk drug manufacturing, stability programs, and aseptic fill-finish. Previous projects have involved vaccines, therapeutics, and diagnostic reagents in an FDA- and CDC-inspected state-of-the-art facility.

BioMARC is part of CSU's Infectious Disease Research Center at the Foothills Campus, a multi-functional campus that includes not only CSU faculty and students working on academic research, but also innovative startup companies.

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