CSU's BioMARC Extends Partnership with Sumagen on HIV Vaccine, Initiates cGMP Manufacturing for Phase II Human Clinical Trial

With a recently signed contract for the manufacturing of an HIV vaccine candidate, CSU's BioMARC and Sumagen Co., Ltd are pleased to report substantial progress on the development of this much needed vaccine. The path to take a novel vaccine candidate from early experiments through the human clinical trials required to gain eventual approval can be a long and difficult process. Dr. John Wyckoff, BioMARC's director, commented on this latest milestone, "Sumagen and BioMARC have had a very productive partnership for several years. At this point in the development, BioMARC has successfully manufactured both pilot-scale and full-scale engineering runs for Sumagen's whole-inactivated HIV vaccine candidate. We are now moving forward with the cGMP manufacturing run to produce the vaccine that will be used in Sumagen's Phase II human clinical trial and our entire team is excited to contribute to this very promising project."

Phase II studies test the efficacy of a vaccine, and can involve up to several hundred patients. This vaccine candidate successfully completed a Phase I clinical study to assess the safety, tolerability, and immune response of the vaccine; of which there were reported no serious adverse effects while boosting antibodies in the volunteers. According to estimates by WHO and UNAIDS, 36.7 million people were living with HIV globally at the end of 2016. That same year, some 1.8 million people became newly infected, and 1 million died of HIV-related causes. An estimated 1.1 million people in the United States had HIV at the end of 2016, the most recent year for which this information is available. Of those people, about 14%, or 1 in 7, did not know they had HIV. Antiretroviral drugs that fight HIV by stopping or interfering with the reproduction of the virus in the body, are helping people live longer and healthier with the virus than ever before, but with a vaccine candidate such as this it could prevent people getting infected in the first place.

The production process utilizes BioMARC infrastructure and expertise working in high containment (Biosafety Level 3) manufacturing under US FDA regulated cGMP conditions. Regular meetings between Sumagen personnel and the BioMARC team which had been optimizing the manufacturing process have helped move the project through key milestones with a strong degree of alignment and with a postive sense of partnership.

About BioMARC

BioMARC is a non-profit contract development and manufacturing organization (CDMO) owned and operated by Colorado State University serving biopharma companies, government agencies, and foundations. BioMARC specializes in biologics manufacturing within high containment to safely handle BSL- 2, BSL-3, and CDC Tier 1 select agents. Development and manufacturing are performed under phase appropriate cGMP conditions for pre-clinical, clinical and commercial products. Services include process and method development, cell, bacteria, and virus banking, bulk drug manufacturing, stability programs, and aseptic fill-finish. Projects involve vaccines, therapeutics, diagnostic reagents, and novel cell based therapies in our FDA and CDC inspected state-of-the-art facility.

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