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Akston Biosciences and LakePharma Announce Strategic Partnership to Manufacture Second-Generation COVID-19 Vaccine

A vaccine for everywhere and everyone in the world, AKS-452 is stable for weeks at room temperature, inexpensive to produce, and suitable for both first-time and booster vaccination

Beverly, MA – Jan. 05, 2021 – [Akston Biosciences](#), which develops new classes of biologic therapeutics, and [LakePharma](#), a leading U.S.-based CRDMO serving the biotechnology community with development and production services, announced today that they have established a strategic partnership. LakePharma will manufacture commercial quantities of Akston's adjuvated COVID-19 vaccine candidate (AKS-452), which is scheduled to begin Phase 1/2 clinical testing later this month.

[AKS-452](#) is the most advanced COVID-19-specific Fc fusion protein vaccine in commercial development and is engineered to induce or boost a Th1/Th2 mixed immune response in patients against the Receptor Binding Domain (RBD) of the novel SARS-CoV-2 coronavirus spike protein. The inherent nature of this construct provides a unique combination of benefits compared to nucleic acid, viral-vectored, and inactivated virus vaccines.

Unlike other vaccines that must be kept refrigerated or even deep-frozen for transport and storage, AKS-452 has been shown to be shelf-stable for weeks at up to 37 degrees Celsius (95°F). This greatly simplifies distribution and is critically important for vaccinating the billions of people not served by sophisticated and costly cold-chain transportation.

Akston has engineered AKS-452 to use conventional antibody manufacturing techniques, such that with multiple batches over one year, a single 2,000-liter production train would be capable of producing over one billion doses.

"Our objective is to provide a practical solution to the problem of vaccinating and, if need be, boosting the immunity of people all over the world against the SARS-CoV-2 virus," said Todd Zion, Ph.D., President & CEO of Akston Biosciences. "Our team realized early on that our fusion protein platform could be used to design a vaccine that checked all the boxes – transportable at ambient temperatures, produced at very low cost, and suitable for repeated dosing if immunity wanes. Partnering with LakePharma gives us great confidence that we can ramp up quickly to deliver large quantities of AKS-452 on a commercial basis."

"LakePharma started working on various COVID-19 activities in February 2020, and was among the first companies to provide a set of recombinantly-produced SARS-CoV-2 spike proteins for diagnostic and therapeutic development," said Hua Tu, Ph.D., President and CEO of LakePharma. "We bring three critical components to this partnership: our experience in making SARS-CoV-2 proteins, our stable CHO-GSN technology, and most importantly, the use of the cGMP manufacturing suite in our Hopkinton, MA facility. We have worked with Akston and its fusion protein therapeutics since 2015, and this experience means we can transition AKS-452 into large-scale production very rapidly."

About Akston Biosciences

Akston Biosciences leverages its novel fusion protein platform to develop and manufacture new classes of biologics, including autoimmune disease therapies, ultra-long-acting insulins, and vaccines. Founded by the team that developed the world's first clinical glucose-responsive insulin at SmartCells, Inc. (sold to Merck & Co. in 2010), Akston partnered with Dechra Pharmaceuticals PLC (DPH) to commercialize AKS-321d, a once-a-week canine insulin therapy. It operates a 1,000 liter GMP biologics manufacturing facility and research laboratory at its Beverly, MA location. www.akstonbio.com.

About LakePharma

LakePharma is a US-based Biologics CRDMO with operations in CA, TX, and MA. This biotech company specializes in the production and evaluation of DNA vectors, viral vectors, cell lines, proteins, antibodies, and conjugates, while providing integrated solutions bridging discovery, engineering, development, and GMP manufacturing. LakePharma has contributed to the development of 200+ therapeutic or diagnostic products and strives to do hundreds more. www.lakepharma.com.

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