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SciTech Development, LLC

SciTech Development, LLC Submits COVID-19 Treatment with Proven Antiviral Activity to U.S. Health & Human Services (HHS)

NanoFenretinide may offer additional support in the battle against the COVID-19 pandemic

(Detroit, MI) April 16, 2020 - SciTech Development, LLC, a clinical stage specialty pharmaceutical company focused on novel, advanced drug delivery mechanisms for use with cancer therapeutics, announced it has submitted a proposal to the Biomedical Advanced Research and Development Authority (BARDA) of HHS for the use of its lead product, nanoFenretinide (ST-001), in the treatment of patients infected with COVID-19 (SARS-CoV-2).

SciTech's patented and differentiated delivery system, SDV, is a proprietary intravenous, phospholipid-based, nanoparticle product. SDV enables drug assets, such as fenretinide, that are water insoluble, to be distributed through the circulatory system in sufficient quantities and doses to reach the target cells and produce a therapeutic effect while maintaining low toxicity levels.

Fenretinide, the first asset that SciTech is combining with SDV, is the active pharmaceutical ingredient (API) in ST-001. Of note, fenretinide has demonstrated preclinical in-vitro antiviral activity against a number of viruses including MERs, Dengue, Zika, West Nile, HIV, and HCV.

These data that fenretinide, and by inference, ST-001, shows activity in the treatment of numerous viruses supports ST-001's consideration as a repurposed drug for treating patients infected with COVID-19. Importantly, fenretinide has been shown to inhibit viral replication in infected cells and has demonstrated modes of action that may help suppress inflammation and the progression to cytokine storms that damage vital organs.

"There are clear unmet therapeutic needs in this current pandemic," said Brian Leyland-Jones, MD, PhD Chief Medical Officer at SciTech. "All reasonable technologies, which could provide meaningful therapeutic benefits for patients infected with COVID-19, should be given an opportunity to be thoroughly and expeditiously studied, especially those with documented potential activity against the virus itself or the deleterious effects of the virus."

SciTech's drug, for proposed use against COVID-19, benefits from the following attributes:

- ***Early availability to the US healthcare system***
- ***Fenretinide's demonstrated activity versus similar coronaviruses***
- ***Readiness of large-scale, US-based production upon positive clinical evaluation of ST-001***
- ***Broad impact of proposed clinical investigations beyond COVID-19***

It is also important to note that fenretinide's extensive safety profile and unique mechanisms of action may support the use of ST-001 as monotherapy as well as in combination therapy, thereby, improving its probability of success in this setting.

In its primary capacity as an oncology drug development company, SciTech's Investigational New Drug Application (IND) for ST-001 treatment of T-cell non-Hodgkin's lymphoma (NHL) was accepted last December. Additionally, the FDA has granted Orphan Drug Designation status for ST-001 in the treatment of two types of NHL: peripheral T-cell lymphoma and cutaneous T-cell lymphoma. Solid preclinical and

clinical data makes the case for the use of fenretinide in the treatment of additional blood disorders and solid tumors such as small cell lung, breast, pancreatic, neuroblastoma and other cancers.

SciTech employs a robust and complementary team that embodies clinical, scientific, regulatory and manufacturing excellence. All team members have a strong track-record in their respective areas of expertise, so that their past experiences offer the required competencies to effectively conduct the proposed development activities of this project.

Leading the effort:

Earle Holsapple - President and Co-Founder; managed the cancer research incubator for Karmanos Cancer Institute

Brian Leyland-Jones, MD, PhD - CMO; Scientific Advisory Board Member for the National Foundation for Cancer Research (NFCR)

About SciTech Development

SciTech Development, LLC is a clinical stage, specialty pharmaceutical, development company currently bringing to market a proven drug for diseases with otherwise limited therapeutic options. SciTech Development is headquartered in the metropolitan Detroit, Michigan area with laboratories at the Sinai Hospital BioIncubator in Baltimore Maryland. <https://www.scitechdevelopment.com>

About HHS BARDA

Biomedical Advanced Research and Development Authority, part of the US Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, was established to aid in securing our nation from chemical, biological, radiological, and nuclear threats, as well as from pandemic influenza and emerging infectious diseases. BARDA supports the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development towards consideration for approval by the FDA and inclusion into the Strategic National Stockpile. BARDA's mission is accomplished through successful public-private partnerships with industry to share risk, improve efficiency and accelerate development all while sustaining a marketplace that guarantees continued access to countermeasures vital to our national security.

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