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Virios Therapeutics Announces Plans to Advance Development of IMC-2 as Treatment for Symptoms Associated with Long-COVID

- Placebo-Controlled Clinical Proof of Concept Data Expected in Mid-2024 -

- Targeting Initiation of IMC-2 Phase 2 program in 2H 2024 -

ATLANTA, Jan. 22, 2024 (GLOBE NEWSWIRE) -- [Virios Therapeutics, Inc.](#) (Nasdaq: VIRI) (the "Company"), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, including [fibromyalgia](#) ("FM") and [Long-COVID](#) ("LC"), today announced plans for advancing IMC-2 (combination of valacyclovir and celecoxib) as a treatment for the fatigue, orthostatic intolerance and other symptoms associated with LC, also known as post-acute sequelae of SARS-CoV-2 infection ("PASC"). The Company is targeting the initiation of a Phase 2 program in the second half of 2024, with data expected in 2025.

"We believe the profound unmet medical need associated with LC symptoms provides a unique and timely opportunity for Virios to advance our combination therapy, IMC-2," said Greg Duncan, Chairman and CEO of Virios Therapeutics. "There are currently no FDA-approved LC treatments, thus IMC-2 has potential to be one of the first therapies for addressing LC symptoms. With FDA agreement that fatigue reduction can serve as the primary endpoint in this program, success on the LC indication may allow extension to other fatigue related illnesses such as Chronic Fatigue Syndrome, thereby expanding our potential market opportunity."

"Virios has provided the Bateman Horne Center with an unrestricted investigational grant to fund their ongoing placebo-controlled 12-week study of the valacyclovir/celecoxib combination in up to 60 LC patients, with data expected by mid-year 2024. In addition, we have received input from the FDA on development requirements and key endpoints associated with advancing IMC-2 into Phase 2 development as a treatment for LC symptoms. We are now taking the organizational steps necessary to prepare for the initiation of a Phase 2 clinical program in the second half of this year. We further expect to provide an update on potential partnership developments later this quarter," Duncan concluded.

About Virios Therapeutics

Virios Therapeutics (Nasdaq: VIRI) is a development-stage biotechnology company focused on advancing novel antiviral therapies to treat diseases associated with a viral triggered abnormal immune response such as fibromyalgia ("FM") and Long-COVID ("LC"). Overactive

immune response related to activation of tissue resident herpesvirus has been postulated to be a potential root cause of chronic illnesses such as FM, irritable bowel syndrome, LC, chronic fatigue syndrome and functional somatic syndromes, all of which are characterized by a waxing and waning manifestation of disease, often triggered by events which compromise the immune system. Our lead development candidates are novel, proprietary, fixed dose combinations of an antiviral compound and celecoxib designed to synergistically suppress herpesvirus replication, with the end goal of reducing virally promoted disease symptoms. IMC-1 has been granted fast track designation by the FDA. For more information, please visit www.virios.com.

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