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Virios Therapeutics' Announces Dosing of First Patient in IMC-2 Long-COVID Treatment Trial

-New Long-COVID Research Program Complements Fibromyalgia Phase 2b Clinical Research Program-

ATLANTA--(BUSINESS WIRE)-- [Virios Therapeutics, Inc.](#) (Nasdaq: **VIRI**), a development-stage biotechnology company focused on advancing novel, combination antiviral therapies to treat debilitating chronic diseases, including [fibromyalgia](#) ("FM"), today announced commencement of enrollment in its exploratory Long-COVID trial. This study is supported via an unrestricted investigational grant to the Bateman Horne Center, a non-profit, interdisciplinary Center of Excellence advancing the diagnosis and treatment of myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS"), FM, post-viral syndromes, and related comorbidities.

The trial will assess the safety and effectiveness of antiviral therapy with Virios' second development combination, IMC-2 (valacyclovir + celecoxib), to treat the symptoms associated with Long-COVID, including fatigue, pain, sleep disruption, anxiety, depression and cognitive function and overall health improvement. IMC-2 is a novel, dual mechanism antiviral therapy combining valacyclovir and celecoxib designed to synergistically suppress herpes virus activation and replication, with the end goal of reducing viral mediated disease burden.

"The dosing of the first patient in this exploratory trial marks an important milestone for Virios, as we develop new combination antiviral therapies to improve care standards for patients suffering from virally mediated diseases," said Greg Duncan, Chairman and Chief Executive Officer of Virios Therapeutics. "Virios has unique potential to create significant value in meeting the medical need for a new treatment that could help the estimated 100 million people worldwide who are suffering from Long-COVID symptoms."

For more information, please visit www.virios.com.

About Virios Therapeutics

Virios Therapeutics (Nasdaq: VIRI) is a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, such as [fibromyalgia](#) ("FM"). Immune responses related to the activation of tissue resident herpes have been postulated as a potential root cause triggering and/or sustaining chronic illnesses such as FM, irritable bowel disease, chronic fatigue syndrome and other functional somatic syndromes, all of which are characterized by waxing and waning symptoms with no obvious etiology. Our lead development candidate ("IMC-1") is a novel, proprietary, fixed dose

combination of famciclovir and celecoxib designed to synergistically suppress herpes virus replication, with the end goal of reducing virally promoted disease symptoms. IMC-1 has been granted fast track designation by the FDA and is currently being tested in a multi-center, randomized, double-blind, placebo-controlled trial (“FORTRESS”), designed to potentially serve as a supportive registrational study. Evidence of IMC-1’s efficacy on a broad spectrum of FM outcome measures was previously demonstrated in a Phase 2a clinical trial.

The Company is pursuing a second development candidate, IMC-2 (valacyclovir and celecoxib), as a potential treatment for managing the fatigue, sleep, attention, pain, autonomic function and anxiety associated with Long-COVID, otherwise known as Post-Acute Sequelae of COVID-19 (PASC). The Company has provided Bateman Horne Center (“BHC”) with an unrestricted investigational grant to conduct this study. BHC is a non-profit, interdisciplinary Center of Excellence advancing the diagnosis and treatment of chronic fatigue disorders, FM, post-viral syndromes, and related comorbidities.

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Forward-Looking Statements

Statements in this press release contain “forward-looking statements,” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “seek,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “suggest,” “target,” “aim,” “should,” “will,” “would,” or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Virios Therapeutics’ current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including risks related to the success, cost and timing of Virios Therapeutics’ preclinical studies and clinical trials; its ability to obtain regulatory approval for IMC-1, IMC-2 and any future product candidates; the company’s need for additional funding; and Virios Therapeutics’ ability to develop and, if approved, commercialize its product candidates. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled “Risk Factors” in the Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Virios Therapeutics, Inc. (VIRI) undertakes no duty to update such information except as required under applicable law.

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