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Virios Therapeutics Completes Enrollment of 425 Patients in Phase 2b “FORTRESS” Clinical Trial for Fibromyalgia

- Top line Data from the FORTRESS Study Expected in September 2022 -

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, announced today that it has completed enrollment in its Phase 2b FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of Herpes Simplex Virus-1 (“HSV-1”)) study, which is a randomized, double-blind evaluation of IMC-1 in patients with fibromyalgia (“FM”).

Virios’ lead antiviral development candidate, orally administered IMC-1, is a novel, proprietary, fixed dose, antiviral therapy combining famciclovir and celecoxib. This dual mechanism antiviral therapy is designed to synergistically suppress herpes virus activation and replication.

“As an innovative new approach to the treatment of fibromyalgia, the potential for IMC-1 to address patients’ symptoms with minimal side effects has motivated investigators, and most importantly patients, to participate in our study, despite the COVID-19 pandemic environment,” said R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Virios Therapeutics. “Based on the high level of interest in our study and the diligent efforts of the trial sites and our clinical operations team, we completed enrollment on plan and expect to report top line results in September 2022.”

Greg Duncan, Chairman and CEO of Virios, stated, “At Virios we believe that activated herpes virus may serve as a potential catalyst for triggering or maintaining diseases like FM. Targeting suppression of herpes virus with combination therapy represents the potential for an exciting new treatment paradigm for FM. Our novel antiviral combination could be a “game changer” for millions of patients suffering from FM, especially given that our market research indicates that only 15% of surveyed physicians treating FM patients report satisfaction with existing treatment options.”

IMC-1 has received “fast track” designation by the U.S. Food and Drug Administration (“FDA”), the first of its kind for a new FM development candidate. The FORTRESS study builds on the statistically significant results from the Company’s previously completed Phase 2a FM clinical study. The previous 143-patient trial demonstrated that IMC-1 met its primary endpoint of pain reduction, improved patient functioning and was statistically better tolerated than placebo.

About the FORTRESS Phase 2b Clinical Trial

Virios Therapeutics is conducting FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV-1). This randomized, double-blind, multi-center, placebo-controlled Phase 2b trial was designed to enroll in excess of 400 patients aged 18-65, all of whom having been diagnosed using the 2016 American College of Rheumatology diagnostic criteria for fibromyalgia. The primary endpoint for this trial is focused on assessment of reduction in pain over time, as measured on a Numerical Rating Scale ("NRS") 24-Hour recall pain intensity scale recorded daily on an electronic diary. Patients record symptoms daily at home for sixteen weeks. In addition to assessing patient's pain reduction, secondary endpoints will include change in fatigue, sleep disturbance, global health status, and patient function.

About IMC-1

IMC-1 is a novel, proprietary, fixed dose combination of famciclovir and celecoxib. This dual mechanism antiviral therapy is designed to synergistically suppress herpes virus activation and replication. IMC-1 combines two specific mechanisms of action purposely selected to inhibit herpes virus activation and replication, thereby keeping the herpes virus in a latent (dormant) state or "down-regulating" herpes virus from a lytic (active) state back to latency. The famciclovir component of IMC-1 inhibits viral DNA polymerase necessary for replication. The celecoxib component of IMC-1 inhibits both cyclooxegenase-2 ("COX-2") and COX-1 enzymes, used by herpes viruses to accelerate their own replication. Virios Therapeutics holds a U.S. "Composition of Matter" Synergistic Patent (US 10,251,853) for the synergistic combination for total daily dose of famciclovir and celecoxib.

About Fibromyalgia

Fibromyalgia ("FM") is a widespread chronic pain disorder, including symptoms of severe pain and fatigue that last for 3 months or longer. FM is also characterized by generalized aching, muscle stiffness, non-restorative sleep, chronic fatigue, depression, cognitive impairment, and disturbances in bowel function. Epidemiologic surveys suggest that FM is present in at least 2% of the U.S. population, and between 3 - 6% of the worldwide population. For more information, please visit www.virios.com/about-fibromyalgia.

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 grant to conduct this study. BHC is 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.

For more information, please visit www.virios.com

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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 completion and timing of the FORTRESS trial or any studies relating to the treatment of Long COVID with IMC-2. 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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