September 19, 2022

Virios Therapeutics Announces Top-Line Results from Phase 2b Study of IMC-1 in Fibromyalgia

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 topline results from its FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of Herpes Simplex Virus-1 ("HSV-1")) study of oral IMC-1 for the treatment of FM.

Overall, the FORTRESS study did not achieve statistical significance on the prespecified primary efficacy endpoint of change from baseline to Week 14 in the weekly average of daily self-reported average pain severity scores comparing IMC-1 to placebo (p=0.302). However, analysis of the data suggests a bifurcation of response based on the timing of patient enrollment in the FORTRESS trial. During the first half of the trial (June 2021 to November 2021), for the patients who were enrolled (n=208) when the Delta variant of COVID-19 was the dominant strain in the U.S., IMC-1 demonstrated no improvement versus placebo-treated patients. Conversely, during the second half of the trial (November 2021 to April 2022), for the patients who were enrolled (n=214) when vaccination rates improved and the less severe Omicron variant of COVID-19 became the dominant U.S. strain, IMC-1-treated patients demonstrated a statistically significant improvement on the primary pain reduction endpoint (p=0.03) at Week 14, as well as a statistically significant improvement in the key secondary PROMIS Fatigue assessment (p=0.006) and the Fibromyalgia Impact Questionnaire-Revised (FIQR) symptoms domain score (p=0.015).

IMC-1 was well-tolerated overall, with only 4.6% of IMC-1 treated patients dropping out due to adverse events, as compared with 8.1% of placebo treated patients. No adverse event category in the IMC-1 group exceeded a 4% rate with the exception of COVID-19 infection. Overall discontinuations were 18.5% in the IMC-1 treated group versus 23% in the placebo treated group. Patients in the FORTRESS trial were randomized one-to-one to either IMC-1 or placebo and patient background demographics and baseline pain scores were well matched.

"We were surprised by the overall primary efficacy result from this study, as we believe this approach continues to have scientific validity and the potential to provide FM patients with a much-needed, well-tolerated therapeutic option. We believe the interplay between different COVID-19 strains and herpes virus activation may be contributing to the differential response we observed in patients enrolled in 2021 versus 2022," stated Greg Duncan, Chairman and CEO of Virios Therapeutics. "Our team and outside advisors are in the process of further analyzing the FORTRESS data, and we will provide an update on our

overall plan to advance the development of IMC-1 as soon as possible."

"Overall, the efficacy data from this trial were not what we had expected," said R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Virios Therapeutics. "We will continue to explore IMC-1's potential as a viable FM treatment option. We would like to thank all of the investigators and patients who participated in FORTRESS for their support of this important research."

Study Overview

The FORTRESS study was a double-blind, placebo-controlled safety and efficacy study of IMC-1 antiviral combination therapy. The final enrollment included 425 female patients, aged 18 to 65, all of whom were diagnosed with FM using the 2016 American College of Rheumatology diagnostic criteria for FM. Study participants were randomized 1-to-1 to either IMC-1 or matching placebo. Three patients were randomized but no data were collected, hence are excluded from our statistical analysis plan. The prespecified primary endpoint for the FORTRESS study was reduction in pain over time as measured by the change from baseline to the Week 14 endpoint in the diary Numerical Rating Scale ("NRS") weekly average of daily self-reported average pain severity scores. Scores range from 0 to 10 where a higher score means worse outcome. Pain was recorded in an electronic diary system that patients used at home on a daily basis. In addition to assessing FM patients' pain reduction, the study also assessed IMC-1's ability to improve symptoms of fatigue and sleep disturbance, and measured improvements in overall global health status and patient function**.**

The Virios Therapeutics team received unblinded data relating to the FORTRESS study on Friday, September 16, 2022.

Conference Call

Virios Therapeutics will host a conference call and live webcast to discuss the FORTRESS study results today, Monday, September 19th, at 8:30 a.m. Eastern Time. The live webcast can be accessed at https://www.webcaster4.com/Webcast/Page/2639/46330. To access the conference call, U.S. participants may call (888) 506-0062 and international participants may call (973) 528-0011. The conference ID number is 449989. A live webcast and replay of the call will also be available on the Virios Therapeutics, Inc. website at www.virios.com. A telephone replay of the conference call will be available until Monday, October 3, 2022. To access this replay, U.S. participants may call (877) 481-4010 and international participants may call (919) 882-2331. The conference ID number for the replay is 46330.

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.

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.

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, timing and results of current and future clinical studies relating to Virios Therapeutics' 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. undertakes no duty to update such information except as required under applicable law.

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