April 24, 2023

Virios Therapeutics Announces Initial FDA Feedback on Proposed IMC-1 Phase 3 Program for Treatment of Fibromyalgia

-Virios' IMC-1 Phase 3 Proposed Program is Considered Acceptable based on Initial FDA Feedback Pending Review of the Final Chronic Toxicology Program Results-

-Final Toxicology Results to be Submitted to FDA in May 2023-

-Company will Provide Material Updates on Further FDA Guidance as Process Proceeds for This Important FDA "Fast-track" Designated Program-

ATLANTA, April 24, 2023 (GLOBE NEWSWIRE) -- Virios Therapeutics, Inc. (Nasdaq: VIRI) (the "Company"), a development-stage biotechnology company focused on advancing novel, combination antiviral therapies to treat debilitating chronic diseases, including fibromyalgia ("FM"), today announced a program summary based on initial feedback from the U.S. Food & Drug Administration ("FDA") on its Phase 3 FM program proposal featuring its lead development candidate IMC-1. 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 fibromyalgia disease symptoms. This feedback was provided following a guidance meeting between the Anesthesiology, Addiction Medicine and Pain Medicine division of FDA and the Company in March 2023.

Key IMC-1 Phase 3 Program Proposal Highlights

- The proposed Phase 3 program consists of four primary components: two adequate and well-controlled clinical studies, one of which would be a full factorial design with each of the individual components of IMC-1 (famciclovir and celecoxib) as separate comparator arms, a long-term safety trial, and a pharmacokinetic/food effect study.

- Based on data from the recently completed FORTRESS Phase 2b trial, the Company proposed a Phase 3 development program targeting community-based FM patients, who have not participated in prior FM trials.

- Initial FDA feedback was that the Company's Phase 3 proposal is acceptable, subject to review of the final results from its recently completed chronic toxicology program. The Company will submit the final toxicology reports and associated data in May 2023.

- An updated IMC-1 Phase 3 program proposal, responsive to FDA guidance, will also be provided once FDA completes its review of the chronic toxicology reports.

There is significant unmet medical need in the FM patient community, as reflected by the

fact that existing treatments do not work for all patients and no new pharmaceutical treatments have been approved by FDA to treat FM over the past decade. The Company will provide material progress updates as it continues to work with FDA with the goal of advancing IMC-1 into Phase 3 development as a potential new treatment option for the FM patient community.

About Virios Therapeutics, Inc.

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 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, 2022, 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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Source: Virios Therapeutics