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Virios Therapeutics Announces Scheduling of FDA Meeting in March 2023 to Discuss IMC-1 Fibromyalgia Phase 3 Program

ATLANTA, Jan. 05, 2023 (GLOBE NEWSWIRE) -- [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"), announced today that its end-of-Phase 2 meeting request with the U.S. Food and Drug Administration ("FDA") to discuss advancing IMC-1 into Phase 3 development as a treatment for FM has been scheduled for mid-March 2023. At this meeting, the Company will discuss with the FDA plans for a Phase 3 program that would support submission of a new drug application for IMC-1 for the treatment of FM. The Company plans to provide a program update by the end of April following the receipt of formal written feedback from the FDA.

The Company believes the safety and efficacy results from its FORTRESS Phase 2b FM study support progression of IMC-1 to Phase 3 development for "new" patients, who represent the vast majority of the FM patient community.

Analysis of the Company's recent FORTRESS Phase 2b FM study data revealed:

- "New" FM patients treated with its novel FM development candidate, IMC-1, who were recruited into FORTRESS via advertising, demonstrated statistically significant reductions in FM related pain, fatigue, anxiety and depressive symptoms and showed an overall improvement in their global health status.
- In contrast, "experienced" FM patients (i.e. patients previously enrolled in FM studies and those with a prior relationship with the FORTRESS study sites), who in the Company's view represent a more treatment refractory/resistant cohort of patients, did not exhibit meaningful treatment benefits.
- "New" patients treated with IMC-1 also exhibited a lower discontinuation rate due to adverse events as compared with "new" patients receiving placebo.
- All patients treated with IMC-1 demonstrated exemplary safety and tolerability in the FORTRESS study.

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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Source: Virios Therapeutics, Inc. (VIRI)



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