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Virios Therapeutics Announces Submission of Final Toxicology Results to Support Proposed Phase 3 Program for Novel Therapy to Treat Fibromyalgia

ATLANTA, May 15, 2023 (GLOBE NEWSWIRE) -- Virios Therapeutics, Inc. (Nasdaq: VIRI) (the "Company"), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, including fibromyalgia ("FM"), today announced that it has submitted final toxicology reports as per Food & Drug Administration ("FDA") request as part of their overall review of the Company's Phase 3 proposal.

Key Highlights

- Proposed Phase 3 program for lead development candidate IMC-1 to the FDA as treatment for FM consisting 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 its 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.

"We are pleased to report that we have submitted the final toxicology program results in support of our proposal to advance IMC-1 to Phase 3 development," said Greg Duncan, Chairman and CEO of Virios Therapeutics. "We will report material FDA feedback on our Phase 3 proposal promptly, as we receive it."

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, a combination of 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 the 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, 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