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Virios Therapeutics Announces Positive Data Demonstrating Improvement in Multiple Long-COVID Symptoms Following Treatment with a Combination of Valacyclovir and Celecoxib in an Exploratory, Open-Label, Proof of Concept Study

ATLANTA, July 17, 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 female patients diagnosed with Long-COVID illness, otherwise known as Post-Acute Sequelae of COVID-19 infection ("PASC"), exhibited clinically and statistically significant improvements in fatigue, pain, and symptoms of autonomic dysfunction and general well-being related to Long-COVID when treated open-label with a combination of valacyclovir and celecoxib ("Val/Cel") for 14 weeks, as compared to a control cohort of female Long-COVID patients matched by age, gender and length of illness and treated with routine care. The statistically significant improvements in PASC symptoms and general health status were particularly encouraging given that the mean duration of Long-COVID illness was two years for both the treated and control cohort prior to enrollment in this trial.

This open-label, single-center, investigator-initiated study was conducted at the Bateman Horne Center ("BHC") with an unrestricted investigational grant. BHC is a non-profit, interdisciplinary Center of Excellence advancing the diagnosis and treatment of chronic fatigue disorders including myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS"), FM, post-viral syndromes, and related comorbidities.

Based on these data, the Company plans to meet with the Food and Drug Administration ("FDA") in the second half of 2023 to discuss opening an investigational new drug application to formally assess treatment of symptoms associated with PASC using a fixed dose combination of valacyclovir and celecoxib.

Key Highlights

- Female patients diagnosed with Long-COVID exhibited clinically and statistically significant improvements when comparing both within the Val/Cel cohort and between study cohorts in:

    - fatigue as measured with both the PROMIS fatigue instrument and a numeric rating scale (“NRS”) for fatigue,
    - pain as measured by a NRS scale for pain,
    - and in autonomic dysfunction symptoms as measured using the Orthostatic Intolerance Questionnaire.
- Two different scales for Patient’s Global Impression of Change documented improvement in overall health when treated with open-label Val/Cel twice daily for 14 weeks.
- Treatment with Val/Cel was generally well tolerated, with an observed safety profile consistent with the known safety profiles of valacyclovir and celecoxib. There were no serious adverse events observed in this study and only one treated patient discontinued treatment due to adverse events, possibly related to Val/Cel treatment. Among those patients receiving Val/Cel, nausea was the most common adverse event. The most common adverse events in the routine care group were headaches and muscle pain.

Prevalence estimates suggest as many as 65 million people worldwide suffer Long-COVID sequelae, including varying degrees of fatigue, cognitive problems, headache, sleep disruption, myalgias, arthralgias, post-exertional malaise and autonomic dysfunction/orthostatic intolerance.

Long-COVID related symptoms result in 2%-4% of the US workforce being unable to work due to their illness, resulting in an economic cost ranging from $170B-$230B, annually, according to a 2022 Brookings Institute estimate.

“Improvements in Long-COVID patients’ related fatigue, autonomic function and overall patient health status suggest the potential for a combination of valacyclovir and celecoxib as a new treatment option for COVID infected patients whose symptoms persist for months, if not years, past their recovery from the initial COVID illness,” said Lucinda Bateman, MD, Founder and Medical Director of the Bateman Horne Center and the study’s principal investigator.

“Given the lack of available treatments to improve care for patients suffering from Long-COVID symptoms, these encouraging results warrant progressing this unique combination treatment into advanced development for post-viral syndromes, including Long-COVID,” said R. Michael Gendreau, MD, PhD, Chief Medical Officer of Virios Therapeutics. “We look forward to engaging the Food and Drug Administration to discuss progressing this novel treatment option into active Phase 2 clinical development.”

About the Study

This open-label, single-center, 14-week investigator-initiated study was designed to explore the safety and efficacy of valacyclovir and celecoxib for the treatment of symptoms associated with Post-Acute Sequelae of COVID-19 infection (“PASC”) in adult female patients. Twenty-two female patients were treated with twice daily doses of valacyclovir and celecoxib, which is theorized to provide potent suppression of suspected tissue-resident

herpes viruses activated by prior infection with the SARS-CoV-2 virus. The physiological response to tissue-resident herpes virus activation is hypothesized to be causally related to symptoms associated with PASC. A comparison cohort of seventeen female Long-COVID patients matched by age and length of illness were concurrently enrolled. The matched routine care group was treated by the Bateman Horne Center providers or recruited from alternative sites where patient care was provided by either their primary care physician or another Long-COVID clinic health professional.

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, myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS"), Post-Acute Sequelae of COVID-19 ("PASC") and other complex disorders, all of which are characterized by multiple symptoms with no obvious etiology. Our lead development candidates ("IMC-1" and "IMC-2") are novel, proprietary, fixed dose combinations of an antiviral compound and celecoxib designed to synergistically suppress herpes virus replication, with the end goal of reducing virally promoted disease symptoms. IMC-1 (fixed dose combination of famciclovir and celecoxib) has been granted fast track designation by the FDA. The Company plans to engage the FDA in the latter half of 2023 with the end goal of filing an investigational new drug application to formally assess IMC-2 (fixed combination of valacyclovir and celecoxib) as a potential treatment for PASC.

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, Inc. (VIRI)

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