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Virios Therapeutics, Inc. Reaches Alignment with FDA on Requirements for Advancing Development Candidate IMC-2 as Treatment for Long-COVID

ATLANTA, Jan. 02, 2024 (GLOBE NEWSWIRE) -- Virios Therapeutics, Inc. (Nasdaq: VIRI) (the "Company"), a development-stage biotechnology company focused on developing novel antiviral therapies to treat debilitating chronic diseases, including fibromyalgia ("FM") and Long-COVID ("LC"), today announced receipt of the Food and Drug Administration's ("FDA") feedback on requirements for advancing IMC-2 (combination of valacyclovir + celecoxib) as a treatment for the fatigue, orthostatic intolerance and other symptoms associated with LC illness, also known as post-acute sequelae of SARS-CoV-2 infection ("PASC").

Key Highlights Associated with FDA Feedback

- The FDA agreed that for the planned Phase 2 proof-of-concept study, Virios can use fatigue as the primary endpoint and orthostatic intolerance as a key secondary endpoint to assess the effectiveness of IMC-2 in treating PASC.
- The FDA recommended assessment of a range of IMC-2 doses, including valacyclovir doses above presently approved dosage strengths, to ensure effective inhibition of reactivated herpesvirus.
- Following the receipt of the FDA's feedback, Virios is currently exploring options to advance the IMC-2 LC Phase 2 research program.
- IMC-2 has the potential to be one of the first approved treatments specifically for LC.

"The National Service for Health Statistics estimates approximately 7% of US adults have had Long-COVID and strikingly, that 3.4% of adults currently have Long-COVID," said Greg Duncan, Chairman and CEO of Virios Therapeutics. "An Australian study found that 74% of the morbidity associated with SARS-COV-2 infection is associated with Long-COVID illness, further highlighting the need for new Long-COVID treatments," Duncan added.

About Virios Therapeutics

Virios Therapeutics (Nasdaq: VIRI) is a development-stage biotechnology company focused on advancing novel antiviral therapies to treat diseases associated with a viral triggered abnormal immune response such as fibromyalgia ("FM") and Long-COVID ("LC"). Overactive immune response related to activation of tissue resident herpesvirus has been postulated to be a potential root cause of chronic illnesses such as FM, irritable bowel syndrome, LC,

chronic fatigue syndrome and functional somatic syndromes, all of which are characterized by a waxing and waning manifestation of disease, often triggered by events which compromise the immune system. Our lead development candidates are novel, proprietary, fixed dose combinations of an antiviral compound and celecoxib designed to synergistically suppress herpesvirus 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.

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. In particular, there can be no assurance that any development partnership or other transaction involving Virios Therapeutics will be completed on favorable terms, or at all. 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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