

# **Virios Therapeutics' Study Featured in Peer-Reviewed Journal Publication Highlighting Association of Herpes Simplex Type 1 Viral Infection with Common Gastrointestinal Disorders, Including in Patients with Comorbid Fibromyalgia**

*Study Demonstrates Potential Utility of Combination Antiviral Drug Therapies, to Treat Patients with Chronic Illnesses such as Fibromyalgia and Irritable Bowel Syndrome*

ATLANTA--(BUSINESS WIRE)-- [Virios Therapeutics, Inc.](#) (Nasdaq: **VIRI**), a development-stage biotechnology company focused on advancing novel, combination antiviral therapies to treat debilitating chronic diseases, including [fibromyalgia](#), today announced the results of a pilot study performed at the University of Alabama, titled "Gastric Herpes Simplex Virus Type 1 Infection is Associated with Functional Gastrointestinal Disorders in the Presence and Absence of Comorbid Fibromyalgia: A Pilot Case-Control Study", were published in the journal *Infection*. These results provide evidence for a potential mechanistic connection between active herpes virus infection and functional gastrointestinal Disorders ("FGID"), with or without comorbid fibromyalgia ("FM"), as well as the potential for combination antiviral therapy to treat patients with FGIDs and FM.

In this study, tissue biopsies were obtained from three groups of volunteers: Group 1 were those with a FGID, such as irritable bowel syndrome, functional dyspepsia, functional constipation as well as comorbid FM; Group 2 were those with FGID only; and Group 3 were control patients without FGID or FM. Epidemiologic studies suggest that FM affects approximately 2% of the population. Previous research published in *Gastroenterology* in 2021 found that FGIDs impact 40% of persons worldwide and affect quality of life and health care use. Neither histological gastritis nor *H. pylori* infection were found to be associated with FGIDs or FM.

"The data presented by Dr. Duffy were from a tissue biopsy study jointly conducted between the University of Alabama and Virios Therapeutics," commented R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Virios Therapeutics. "The study examined gastric mucosa biopsies from three cohorts: patients with FGID, patients with both FGID and FM, and control patients. Biopsy specimens were analyzed for the presence of active herpes virus infections. As is discussed in the publication, there was a marked increase in the presence of actively replicating herpes simplex virus type 1 ("HSV-1") in gastric mucosal tissue from the FGID

and the FGID and FM patient groups as compared to control patients.”

“This finding highlights the potential role of activated HSV-1 as a potential root cause of common chronic gastrointestinal disorders. Importantly, neither histological gastritis nor *H. pylori* infection were found to be associated with FGIDs or FM. This publication provides further visibility to the medical community of the potential utility of combination antiviral drug therapies, such as IMC-1, for patients with chronic illnesses such as FM and irritable bowel syndrome (“IBS”), which are often described as functional disorders,” concluded Dr. Gendreau.

**Title:** Gastric Herpes Simplex Virus Type 1 Infection is Associated with Functional Gastrointestinal Disorders in the Presence and Absence of Comorbid Fibromyalgia: A Pilot Case-Control Study

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**Conclusions:** Analysis of gastric mucosa biopsies revealed a significant positive association between actively replicating gastric HSV-1 and multiple functional gastrointestinal disorders, with and without concomitant FM. FGIDs including IBS, functional dysphagia, and functional dyspepsia may be related to active HSV-1 infection. Further investigation into the prevalence and possible causal nature of this association is warranted.

For more information, please visit [www.virios.com](http://www.virios.com).

## 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 and is currently being tested in a multi-center, randomized, double-blind, placebo-controlled trial (“FORTRESS”), designed to potentially serve as a supportive registrational study. Evidence of IMC-1’s efficacy on a broad spectrum of FM outcome measures was previously demonstrated in a Phase 2a clinical trial.

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 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](http://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,” “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 success, cost and timing of Virios Therapeutics’ preclinical studies and clinical trials; its ability to obtain regulatory approval for IMC-1, IMC-2 and any future product candidates; the company’s need for additional funding; and Virios Therapeutics’ ability to develop and, if approved, commercialize its 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. (VIRI) undertakes no duty to update such information except as required under applicable law.

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