

May 24, 2021



## Virios Therapeutics Announces Oral Presentation of Clinical Data at Digestive Disease Week® (DDW)

ATLANTA--(BUSINESS WIRE)-- [Virios Therapeutics, Inc.](#) (Nasdaq: **VIRI**), a clinical-stage biotechnology company focused on advancing novel antiviral therapies to treat diseases associated with virally triggered or maintained immune responses, announced today that clinical data was highlighted in an oral presentation at Digestive Disease Week® (“DDW”) 2021, the premier global meeting for physicians, researchers and industry in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery, which was held virtually May 21 – 23, 2021.

“The data presented by Dr. Duffy comprised 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 functional gastrointestinal disorders (“FGID”), patients with both FGID and fibromyalgia (FM), and control patients. Biopsy specimens were analyzed for the presence of active herpesvirus infections. As is discussed in the presentation, there was a marked increase in the presence of actively replicating herpes simplex virus type 1 (HSV-1) in gastric mucosal tissue from FGID and FGID + FM patient groups as compared to control patients.”

“This finding highlights the potential role of activated HSV-1 as a potential root cause of chronic gastrointestinal disorders. Furthermore, this presentation provides further visibility to the medical community on the potential utility of combination antiviral drug therapies, such as IMC-1, for patients with chronic illnesses such as fibromyalgia (“FM”) and irritable bowel syndrome (“IBS”), which are characterized by waxing and waning manifestation of disease,” concluded Dr. Gendreau.”

**Session:** Clinical Science Late-Breaking Abstract Plenary

**Title:** Active Herpes Simplex Virus Type 1 Infection of the Gastric Mucosa is Associated with Functional Gastrointestinal Disorders: A Pilot Case-Control Study (Abstract # 3581012)

**Presenter:** Carol Duffy, Ph.D., University of Alabama

**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 IMC-1**

IMC-1 is a novel, proprietary, fixed dose combination of famciclovir and celecoxib. This dual mechanism antiviral therapy is designed to synergistically suppress Herpes Simplex Virus-1 ("HSV-1") activation and replication, with the end goal of reducing viral mediated disease burden. IMC-1 combines two specific mechanisms of action purposely selected to inhibit HSV-1 activation and replication, thereby keeping HSV-1 in a latent (dormant) state or "down-regulating" HSV-1 from a lytic (active) state back to latency. The famciclovir component of IMC-1 inhibits viral DNA polymerase necessary for replication. The celecoxib component of IMC-1 inhibits both cyclooxygenase-2 ("COX-2") and COX-1 enzymes, used by HSV-1 to accelerate its own replication. Virios Therapeutics holds a U.S. "Composition of Matter" Synergistic Patent (US 10,251,853) for the synergistic combination for total daily dose of famciclovir and celecoxib.

## **About Virios Therapeutics**

Virios Therapeutics (Nasdaq: **VIRI**) is a clinical-stage biotechnology company focused on advancing novel, dual mechanism antiviral therapies to treat conditions associated with virally triggered or maintained immune responses, such as fibromyalgia ("FM"). Immune responses related to the activation of tissue resident Herpes Simplex Virus-1 ("HSV-1") have been postulated as a potential root cause triggering and/or sustaining chronic illnesses such as FM, irritable bowel disease ("IBS"), 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 HSV-1 replication, with the end goal of reducing virally promoted disease symptoms.

Evidence of IMC-1's efficacy on a broad spectrum of FM outcome measures was previously demonstrated in a Phase 2a clinical trial. These trial results are suggestive that IMC-1 may represent a new and novel treatment for fibromyalgia. 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 Phase 2b trial ("FORTRESS") designed to set the stage for registrational studies. The company is led by an executive team highly experienced in the successful development and commercialization of novel therapies. For more information, please visit [www.virios.com](http://www.virios.com).

## **Forward-Looking Statements**

Statements in this press release contain "forward-looking statements" 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 completion and timing of the Phase 2b trial.

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, 2020 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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