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# Virios Therapeutics Presents Phase 2a Fibromyalgia Trial Data on Efficacy Analyses of Key Secondary Endpoints at the EULAR European Congress of Rheumatology

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 from its Phase 2a trial of IMC-1 in fibromyalgia (“FM”) is featured in a poster presentation (poster POS0017) at the annual EULAR European Congress of Rheumatology, a renowned forum for interaction between medical doctors, scientists, people with arthritis/rheumatism, health professionals and representatives of the pharmaceutical industry worldwide, which is being held virtually June 2 - 5, 2021. The company’s poster has been selected to be highlighted in a guided tour entitled “Epidemiology and treatment of pain in Rheumatic and Musculoskeletal Disorders.”

IMC-1 is a novel, proprietary, fixed dose, antiviral therapy combining 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.

“Given that FM is associated with a broad spectrum of symptoms beyond pain, it is important to understand the impact of IMC-1 on other FM-related symptoms,” commented R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Virios Therapeutics. “In our Phase 2a FM trial, in addition to meeting the primary endpoints of greater tolerability and significantly greater pain reduction compared with placebo, patients treated with IMC-1 reported significantly greater improvement compared with placebo on the Revised Fibromyalgia Impact Questionnaire (“FIQ-R”) total score and on all three FIQ-R domains. These secondary endpoint results suggest that IMC-1 may represent a promising treatment option not only for alleviating pain, but also for improving other symptoms associated with FM, such as stiffness, sleep quality, depression, anxiety and fatigue,” surmised Dr. Gendreau.

**Title:** IMC-1, a Fixed Dose Combination of Famciclovir and Celecoxib, Improves Common Symptoms Associated with Fibromyalgia in Addition to Pain: Post Hoc Analysis of a Phase 2a Trial

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**Conclusions:** In this post hoc analysis of a Phase 2a trial of IMC-1 in patients with FM,

patients treated with IMC-1 reported significantly greater improvement compared with placebo on FIQ-R total scores and on all FIQ-R domains. Patients receiving IMC-1 treatment reported significantly greater improvements versus placebo on the FIQ-R symptom items for stiffness, sleep quality, depression, and anxiety. Improvements in patient global assessments and in fatigue assessments provide additional evidence for the beneficial effects of IMC-1 on FM related symptoms. These results suggest that IMC-1 may represent a promising treatment option not only for alleviating pain, but also for improving other symptoms associated with FM.

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 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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