

June 9, 2021



Virios Therapeutics Highlights Safety Data from Phase 2a Fibromyalgia Trial at the International Association for the Study of Pain (IASP) World Congress

ATLANTA--(BUSINESS WIRE)-- [Virios Therapeutics, Inc.](https://www.virios.com) (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 data from the company's Phase 2a clinical trial PRID-201 demonstrated that IMC-1 was better tolerated than placebo in patients with fibromyalgia ("FM"). This result is highlighted in a poster presentation at the International Association for the Study of Pain (IASP) World Congress, being held virtually June 9 - 11, 2021 and June 16 - 18, 2021.

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.

"There is a clear medical need for new, safe and effective treatments with the potential to improve care for the estimated 10 - 20 million FM patients in the U.S. and more than 200 million worldwide," commented R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Virios Therapeutics. "Our Phase 2a clinical trial data showed that IMC-1 treated patients had higher overall completion rates and lower rates of discontinuation due to adverse events, as compared with placebo-treated patients. This is an especially encouraging result when viewed in the background of current patient and provider dissatisfaction with the generally poor tolerability of existing approved FM treatments," concluded Dr. Gendreau.

Title: The Safety of IMC-1 in Patients with Fibromyalgia: Phase 2a Study Results

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Conclusions: IMC-1 exhibited an encouraging safety profile, as AEs occurred at a lower rate and were less severe in the IMC-1 treatment group compared with placebo. The discontinuation rate due to AEs was nearly 3-fold higher in patients receiving placebo compared with patients receiving IMC-1, suggesting that treatment with IMC-1 was unusually well-tolerated. In this study, IMC-1 demonstrated significant reductions in pain, fatigue, and other important symptoms in patients with FM. These results suggest that IMC-1 may offer a promising and well-tolerated option to treat patients with FM.

For more information, please visit 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.

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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