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Virios Therapeutics Announces Dosing of First Patient in Phase 2b Trial Evaluating IMC-1 in Patients with Fibromyalgia

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 dosing of the first patient in its Phase 2b clinical trial, referred to as FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV-1), evaluating IMC-1 in patients with fibromyalgia.

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 currently widespread dissatisfaction among fibromyalgia patients, healthcare providers and payers with the existing FDA approved medications for the management of fibromyalgia, most notably related to their generally poor tolerability,” commented R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Virios Therapeutics. “We are excited about the FORTRESS trial as we are testing optimized doses of IMC-1, and we will be measuring patients’ fibromyalgia related pain on a daily basis. Based on industry standard fibromyalgia patient recruitment rates, we expect to complete the trial and announce top line results in mid-2022.”

“The dosing of the first patient in this Phase 2b trial marks an important milestone for Virios, as we develop new, combination antiviral therapies to improve care standards for patients suffering from chronic diseases like fibromyalgia and irritable bowel syndrome,” said Greg Duncan, Chairman and Chief Executive Officer of Virios Therapeutics. “Virios has a unique potential to create significant value in meeting the medical need for a new, safe and effective treatment to help the large market of 10-20 million fibromyalgia patients in the U.S. and more than 200 million worldwide.”

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 cyclooxegenase-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 the IMC-1 Phase 2b Clinical Trial

Virios Therapeutics is conducting FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV-1). This randomized, double-blind, multi-center, placebo-controlled Phase 2b trial is expected to enroll approximately 460 patients aged 18-65, all of whom having been diagnosed using the 2016 American College of Rheumatology diagnostic criteria for fibromyalgia. The primary endpoint for this trial will focus on reduction in pain over time, as measured daily by the Numerical Rating Scale (“NRS”) 24-Hour Recall scale via an electronic diary that the patient will use at home for sixteen weeks. In addition to assessing patient’s pain reduction, secondary endpoints will include change in fatigue, sleep disturbance, global health status, and patient function.

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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Source: Virios Therapeutics, Inc. (VIRI)