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Virios Therapeutics Highlights Clinical Sites Fully Operational in Phase 2b Fibromyalgia Study Featuring FDA “Fast Track” Review Designated Antiviral Therapy, Oral IMC-1

ATLANTA--(BUSINESS WIRE)-- Virios Therapeutics, Inc. (Nasdaq: **VIRI**), a clinical-stage biotechnology company focused on advancing novel antiviral therapies to treat chronic pain and fatigue related diseases, announced today that all 41 sites involved in its ongoing 460 patient Phase 2b fibromyalgia (FM) trial are now fully activated and enrolling patients. This trial builds on the encouraging results from the Company’s previously completed IMC-1 phase 2a FM clinical study. The 143-patient Phase 2a trial demonstrated that VIRI’s lead antiviral development candidate, orally administered IMC-1, met its primary endpoint of pain reduction and was statistically better tolerated than placebo.

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. It is the Company’s hypothesis that HSV-1 related immune responses can serve as a catalyst for symptoms commonly associated with FM, irritable bowel syndrome (IBS) and fatigue related disorders. This hypothesis is supported by both clinical and mechanistic data, the latter of which has suggested that HSV-1 is actively replicating in the tissue of patients diagnosed with FM and chronic GI disorders, such as IBS.

“We are pleased that enrollment in our FORTRESS study is proceeding as planned and that all of our sites are now able to recruit patients,” said Dr. R. Michael Gendreau, Virios’ Chief Medical Officer.

Dr. Gendreau continued, “Data from our prior clinical work has been presented in several recent medical meetings. These data demonstrate that in our Phase 2a FM trial, in addition to meeting the primary endpoint of significantly greater pain reduction compared with placebo, patients treated with IMC-1 reported significantly greater improvement on the Revised Fibromyalgia Impact Questionnaire (“FIQ-R”) total score showed significant improvement on all three of the FIQ-R domains, and also showed statistical significance on the patient global impression of change (PGIC). In addition, treatment with IMC-1 was exceptionally well tolerated in this study. These secondary endpoint results, combined with excellent tolerability, 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.”

The Company anticipates reporting top line results from the currently enrolling FORTRESS Phase 2b FM trial in mid-2022.

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. 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 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.

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 460 patient 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," "suggest," "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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