December 1, 2021

Virios Therapeutics Achieves Over 50% Enrollment Milestone in its Phase 2b Clinical Trial for Fibromyalgia

- **New Potential Treatment Targets Millions of Fibromyalgia Patients Worldwide**
- **First Ever FDA "Fast Track" Designation for Fibromyalgia Development Candidate**
- **Phase 2b Clinical Trial Builds on Positive Phase 2a Data**

ATLANTA--(BUSINESS WIRE)-- Virios Therapeutics, Inc. (Nasdaq: **VIRI**), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, including fibromyalgia, announced today that more than 50% of the patients planned for the Phase 2b FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV-1) study have been randomized.

The FORTRESS study is a randomized, double-blind evaluation of IMC-1 in patients with fibromyalgia ("FM"). Worldwide, FM affects 3-6% of the population and is characterized by widespread chronic pain and multiple symptoms often including severe fatigue, sleep disruption and cognitive dysfunction. Based on Virios market analysis, we estimate that only 15% of FM treatment prescribers report satisfaction with existing treatment options. The FORTRESS study builds on the statistically significant results from the Company's previously completed Phase 2a FM clinical study. The 143-patient Phase 2a trial demonstrated that IMC-1 met its primary endpoint of pain reduction and was statistically better tolerated than placebo.

"We are pleased that enrollment in our FORTRESS trial is progressing rapidly, with careful patient selection and the support of more than 40 U.S. clinical sites," said R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Virios Therapeutics. "We are very grateful for the physicians at these sites and their patients for their commitment and willingness to participate in this critical FM trial, especially during a pandemic. Reaching this enrollment milestone on a timely basis indicates that we are currently on track to report top line results in Q3 of 2022."

Greg Duncan, Chairman and CEO of Virios, stated, "Fibromyalgia is a chronic disease that affects 10 million patients in the U.S. As many as 40% of FM patients are being treated with opioids, according to market surveys. This is particularly troubling given FM patients treated with opioids have been shown to experience worse outcomes among multiple assessment domains. Consistent with our mission, Virios Therapeutics is developing the non-opioid IMC-1 with the end goal of advancing care for hundreds of millions of patients globally in need of new FM treatment options."

Virios' lead antiviral development candidate, orally administered 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. The uniqueness of this approach has garnered IMC-1 "fast track" designation by the U.S. Food and Drug Administration (FDA), the first of its kind for a new FM development candidate. 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 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.

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 development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, 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”, within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, 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 FORTRESS 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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Dave Gentry
1-800-733-2447
+1-407-491-4498
dave@redchip.com
or
ir@virios.com

Source: Virios Therapeutics, Inc. (VIRI)