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Virios Therapeutics Announces Research Collaboration Exploring the Potential of Combination Antiviral Therapy for Treating Long COVID

- Long COVID Impacts Up To 30% of COVID-19 Patients
- Activation of Dormant Herpes Virus Infections are Hypothesized as a Potential Trigger of Long COVID
- Combination Therapy with IMC-2 (valacyclovir and celecoxib) Expands Virios' Pipeline

ATLANTA--(BUSINESS WIRE)-- [Virios Therapeutics, Inc.](#) (Nasdaq: **VIRI**), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat chronic diseases, including [fibromyalgia](#), announced today a collaboration with the Bateman Horne Center ("BHC") of Salt Lake City, Utah, to explore the role of combination antiviral therapy in Long COVID, otherwise known as Post-Acute Sequelae of COVID-19. The Bateman Horne Center is a non-profit, interdisciplinary Center of Excellence advancing the diagnosis and treatment of myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS"), [fibromyalgia](#) ("FM"), post-viral syndromes, and related comorbidities.

Virios Therapeutics, Inc. is providing BHC with an unrestricted grant for an investigator-sponsored study to explore the therapeutic potential of combination antiviral therapy with Virios' second development candidate, IMC-2. The study will evaluate changes in common Long COVID symptoms such as fatigue, sleep, attention, pain, autonomic function and anxiety.

"We are pleased to support the Bateman Horne Center, a leading clinical research center in post-viral syndromes, as they study the therapeutic potential of IMC-2 to ease the burden of Long COVID, which is an emerging healthcare crisis," said Greg Duncan, Chairman and CEO of Virios Therapeutics Inc.

According to the World Health Organization, COVID-19 has caused more than 373 million infections and more than 5.6 million deaths as of January 2022. Published estimates in the scientific literature suggest that up to 30% will experience Long COVID symptoms. It is estimated that one in three patients who develop Long COVID symptoms were asymptomatic during their acute COVID-19 infection. The mechanisms by which COVID-19 causes lingering symptoms are not well understood. Potential triggers for long term symptoms might include:

- Immune-system dysregulation triggered by the COVID-19 virus, including increased production of autoantibodies,
- Lingering or re-infection with COVID-19 variants, and

- Co-infection or activation of previous viral infections that had become dormant

“Most adults are infected with normally harmless dormant viruses contracted years earlier,” said R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Virios Therapeutics. “It is becoming increasingly clear that COVID-19 acutely depresses our immune system, which may allow for reactivation of neurotrophic pathogens such as viruses in the herpes family.”

Virios’ lead antiviral development candidate, orally administered IMC-1, is a novel, proprietary, fixed dose, antiviral therapy combining famciclovir and celecoxib. The ongoing Phase 2b FORTRESS study is a randomized, double-blind evaluation of IMC-1 in patients with FM. 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.

The Company’s dual mechanism antiviral development candidates are designed to synergistically suppress herpes virus 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.

About IMC-1 and IMC-2

IMC-1 is a novel, proprietary, fixed dose combination of famciclovir and celecoxib. This dual mechanism antiviral therapy is designed to synergistically suppress herpes virus activation and replication. IMC-1 combines two specific mechanisms of action purposely selected to inhibit herpes virus activation and replication, thereby keeping herpes viruses in a latent (dormant) state or “down-regulating” herpes viruses 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 herpes viruses to accelerate their replication.

IMC-2 is a novel, proprietary combination of valacyclovir and celecoxib that combines two specific and synergistic mechanisms of action, purposely selected to inhibit herpes virus activation and replication. IMC-2 keeps herpes viruses in a latent (dormant) state or “down-regulates” herpes viruses from a lytic (active) state back to latency. The valacyclovir component of IMC-2 inhibits viral DNA polymerase necessary for replication. The celecoxib component of IMC-2 inhibits both COX-2 and COX-1 enzymes, used by herpes viruses to accelerate their replication.

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 FM. Immune responses related to the activation of tissue resident herpes 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 herpes 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.

Virios Therapeutics, Inc. is providing BHC with an unrestricted grant to explore the therapeutic potential of combination antiviral therapy with the Company's second development candidate, IMC-2, in managing the fatigue, sleep, attention, pain, autonomic function and anxiety associated with Long COVID.

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.

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About Bateman Horne Center of Excellence

The Bateman Horne Center ("BHC") is a non-profit, interdisciplinary Center of Excellence where clinical care, research, and education meet to collectively advance the diagnosis and treatment of myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS"), fibromyalgia ("FM"), post-viral syndromes, and related comorbidities.

BHC fosters clinical success for the care and treatment of ME/CFS and FM using clinical intelligence derived from data analytics of patient records in the quest for improved medical care for current and future patients.

BHC engages collaborative partnerships to inform healthcare consumers and providers to deliver enhanced quality and improved outcomes through innovation, applied technology, and efficient distribution of knowledge.

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 any studies relating to the treatment of Long COVID with IMC-2. 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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