

August 9, 2023



Virios Therapeutics Announces Plans to Advance Lead Candidate IMC-1 to Phase 3 Development as a New Treatment Option for Fibromyalgia

ATLANTA, Aug. 09, 2023 (GLOBE NEWSWIRE) -- [Virios Therapeutics, Inc.](#) (Nasdaq: VIRI) (the "Company"), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases such as [fibromyalgia](#) ("FM") and Long-COVID, today announced that the Food & Drug Administration ("FDA") communicated that, following their initial review of the Company's chronic toxicology program, the program's studies appear adequate to support the safety of IMC-1 at the dose proposed by the Company for chronic use. With this critical feedback in hand, the Company plans to initiate its proposed pharmacokinetic and food effect study ("pK") this year, while concurrently resubmitting a final Phase 3 program outline and study protocols for FDA review. Following completion of the pK study, the goal will be to begin enrollment in the first fibromyalgia Phase 3 safety and efficacy study in mid-2024.

Key Highlights and Upcoming Milestones

- The Company plans to execute the pK study in males and females as a precursor to the FM studies with an updated IMC-1 dose and formulation, which is intended to enable the Company to take advantage of all of the efficiencies afforded with utilization of the 505(b)(2) regulatory pathway.
- Consistent with the previously proposed Phase 3 plan, the Company will concurrently submit its final Phase 3 program outline and associated study protocols to FDA, to progress the following:
 - Two adequate and well-controlled clinical studies; and
 - A long-term extension trial to support chronic administration of IMC-1.
- Based on the results from its recently completed FORTRESS Phase 2b trial, the Company has designed a Phase 3 development program targeting community-based FM patients who have not participated in prior FM trials.

"We look forward to initiating our pK study with the updated formulation of IMC-1 while finalizing the protocols and procedures required for Phase 3 development of IMC-1 as a treatment for FM. The safety and efficacy results from the FORTRESS trial, along with the chronic toxicology program results, have enabled us to define a clinical trial program as well as a formulation and dose of IMC-1 to enhance our chances for success," said R. Michael Gendreau, Chief Medical Officer of Virios Therapeutics.

The Company will share more information about its FM Phase 3 program during its earnings update on Thursday, August 10, 2023 at 8:30 a.m. ET.

About Virios Therapeutics

Virios Therapeutics (Nasdaq: VIRI) is a development-stage biotechnology company focused on advancing novel antiviral therapies to treat diseases associated with a viral triggered abnormal immune response such as [fibromyalgia](#) ("FM") and Long-COVID. Overactive immune response related to activation of tissue resident herpesvirus has been postulated to be a potential root cause of chronic illnesses such as FM, irritable bowel syndrome, Long-COVID, chronic fatigue syndrome and functional somatic syndromes, all of which are characterized by a waxing and waning manifestation of disease, often triggered by events which compromise the immune system. Our lead development candidates are novel, proprietary, fixed dose combinations of an antiviral compound and celecoxib designed to synergistically suppress herpesvirus replication, with the end goal of reducing virally promoted disease symptoms. IMC-1 (fixed dose combination of famciclovir and celecoxib) has been granted fast track designation by the FDA. The Company plans to engage the FDA in the latter half of 2023 with the goal of filing an investigational new drug application to formally assess IMC-2 (fixed combination of valacyclovir and celecoxib) as a potential treatment for Long-COVID sequelae.

For more information, please visit www.virios.com.

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Forward-Looking Statements

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for the year ended December 31, 2022, filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Virios Therapeutics, Inc. undertakes no duty to update such information except as required under applicable law.

Contact:

IR@Virios.com



Source: Virios Therapeutics