

AIM ImmunoTech Announces that Analysis of AMP-518 Complete Clinical Patient Data Underscores Ampligen's Potential to Improve the Post-COVID Condition of Fatigue

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Company is planning a follow-up clinical trial with a focused subject population of moderate-to-severe Post-COVID-related fatigue

Ocala, Fla., Sept. 11, 2024 (GLOBE NEWSWIRE) -- **AIM ImmunoTech Inc.** (NYSE American: AIM) ("AIM") today announced that an analysis of the complete clinical patient data from the AMP-518 clinical trial supported the Company's belief in Ampligen as a potential therapeutic for people with the moderate-to-severe Post-COVID condition of fatigue, and that this would be the likely subject population for AIM's planned follow-up clinical trial.

AIM had **previously reported** positive topline results from its AMP-518 Phase 2 clinical trial. In further analyzing the results of AMP-518, AIM determined that, in this study, patients with Long COVID were, on average, able to walk farther in a Six-Minute Walk Test ("6MWT") when compared to subjects who received a placebo. The 6MWT measured the distance a subject was able to walk in six minutes as a baseline and then again at 13 weeks. A clear signal of significant potential ($p < 0.02$, two-tailed T-test) was observed in Ampligen-treated subjects with a baseline 6MWT less than 205 meters, who saw a mean improvement of 139 meters, compared to a mean improvement of 91 meters in the corresponding part of the group who received the placebo. AIM therefore believes that any future trial design should focus on Ampligen's therapeutic potential for subjects whose Long COVID-related fatigue can be categorized as moderate or worse.

AIM Medical Officer Charles Lapp, MD, stated: "Approximately two hundred meters in six minutes is generally agreed upon as the difference between a person being "home ambulatory" or "community ambulatory." To put that

simply, this tells us that a person who can make that walk is someone who is healthy and active enough to go out in their community, but people who cannot make that distance are far more likely to be homebound. For this reason, we believe that Ampligen also has the greatest potential value for Long COVID subjects whose fatigue is moderate to severe.”

Dr. Lapp was recently appointed AIM's lead Medical Officer, having joined the Company in April 2024 to help lead development efforts for Ampligen as a potential treatment for Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) and Long COVID. David Strayer, MD, will continue to serve as a Medical Officer of AIM on a part-time basis. Christopher F. Nicodemus, MD, FACP, who is a nationally renowned immuno-oncologist, will also be joining AIM as a consultant on September 15, 2024; Dr. Nicodemus is a member of AIM's Scientific Advisory Board.

In related news, AIM Scientific Officer Christopher McAleer, PhD, was invited to be a panelist on Study Design at the National Institutes of Health's "RECOVER Treating Long COVID – Navigating the Pathway Forward" meeting, being held September 23-25, 2024.

For more information about AMP-518, please visit **ClinicalTrials.gov** and reference identifier **NCT05592418**.

About AIM ImmunoTech Inc.

AIM ImmunoTech Inc. is an immuno-pharma company focused on the research and development of therapeutics to treat multiple types of cancers, immune disorders and viral diseases, including COVID-19. The Company's lead product is a first-in-class investigational drug called Ampligen® (rintatolimod), a dsRNA and highly selective TLR3 agonist immuno-modulator with broad spectrum activity in clinical trials for globally important cancers, viral diseases and disorders of the immune system.

For more information, please visit **aimimmuno.com** and connect with the Company on **X**, **LinkedIn**, and **Facebook**.

Cautionary Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). Words such as "may," "will," "expect," "plan," "anticipate," "continue," "believe," "potential," "upcoming" and other variations thereon and similar expressions (as well as other words or expressions referencing future events or circumstances) are intended to identify forward-looking statements. Many of these forward-looking statements involve a number of risks and uncertainties. Data, pre-clinical success and clinical success seen to date does not guarantee that Ampligen will be approved for the commercial treatment of Long COVID or Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The Company urges investors to consider specifically the various risk factors identified in its most recent Form 10-K, and any risk factors or cautionary

statements included in any subsequent Form 10-Q or Form 8-K, filed with the U.S. Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Among other things, for those statements, the Company claims the protection of the safe harbor for forward-looking statements contained in the PSLRA. The Company does not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

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