AISA Pharma Announces Positive Data Safety Monitoring Board Review of First Phase 2 Data of Profervia® to treat Raynaud's Disease in Scleroderma Patients

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Company to Move Forward with Key U.S. Regulatory Applications – Investigational New Drug and Orphan Drug Designation

BOSTON, July 26, 2022 — Aisa Pharma, Inc. a privately-funded, clinical-stage biopharmaceutical company, today announced that the Data Safety Monitoring Board (DSMB) for the RECONNOITER Phase 2 study of Aisa's Profervia® once-daily novel, oral calcium-channel antagonist has met and unanimously recommended continuing to the next stage in the trial and approved a go-forward dose level. In addition, the DSMB found no safety issues of concern and encouraging early efficacy trends in this first-ever clinical trial of the drug in the Phase 2 dose-finding portion of the study of patients with secondary Raynaud's disease associated with scleroderma. The company will now begin Part B, a double-blind, prospective, placebo-controlled, randomized crossover study, which will randomize additional patients.

Scleroderma is the most fatal of the autoimmune diseases and 95% of patients experience Raynaud's symptoms, which are debilitating, painful attacks commonly felt in the fingers that may occur multiple times daily and greatly diminish patients' quality of life. Aisa's study is examining whether its proprietary therapy can reduce the frequency, severity, and duration of these attacks, modify the course of the disease, and improve other symptoms of Scleroderma.

Based on the DSMB recommendation, the Phase 2 study will continue from the first dose-finding portion (Part A) into its second double blind randomized crossover stage (Part B) with the selected Profervia® dose. The DSMB reviewed data by treatment group assignment and concluded that no safety issues of concern were demonstrated in the first 27 patients. The DSMB remarked that the treatment appeared to be much better tolerated than their own and published clinical trial experience of currently used calcium channel blocker therapy for treating Raynaud's in Scleroderma patients, The DSMB also accelerated the study, recommending that the study had met its goals for the Part A dose-finding parallel group assignment first phase and that the study proceed directly into the double-blind

crossover Part B of the study, recalculating the sample size based on the treatment effect seen and omitting an additional 9 patients originally planned for Part A.

"We are excited with this first DSMB review of the RECONNOITER data," said Andrew Sternlicht, M.D., the CEO and Founder of Aisa Pharma. "We believe Profervia® has the potential to produce clinically meaningful benefit in a safe and well tolerated oral daily treatment, which we hope will dramatically improve the lives of thousands of patients with scleroderma who currently have no approved options to treat their debilitating Raynaud symptoms. Given the data to date and the results of this DSMB Meeting, we intend to move forward with regulatory filings in the U.S., including applying for Orphan Drug designation and opening an IND – which we hope to complete by the first quarter of 2023."

About Profervia®:
Profervia® is a reformulated form of Cilnidipine, a novel calcium channel blocker (CCB) only approved in several Asian countries for treating hypertension, but never approved anywhere in the World for the treatment of Scleroderma and Raynaud's. Cilnidipine increases blood flow to peripheral organs and tissues; unlike currently approved CCBs in the U.S., it targets a receptor now known to have a sentinel role in painful conditions in peripheral tissues as well as some intrinsic analgesic properties as well as improving function in target organs like the vasculature, heart and kidney that contribute to morbidity and mortality in Scleroderma patients. In previously conducted large ex-U.S. studies of hypertension treatment, cilnidipine is better tolerated than current U.S.-approved calcium channel blockers, that are used off-label to treat Raynaud's symptoms in patients. Aisa is investigating cilnidipine for use in scleroderma and Raynaud's treatment.

About Aisa Pharma Inc.
Aisa is a privately-funded biopharmaceutical company located in Boston, MA. Aisa's initial therapeutic under development is Profervia®, intended for use in patients with Secondary Raynaud's symptoms primarily due to scleroderma.

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