Regulatory Authorities in China and Japan Approve Clinical Trials for Anthos Therapeutics' Dual-Acting Factor XI/XIa Inhibitor Abelacimab

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Fewer than 26% of Chinese Patients with Atrial Fibrillation are Prescribed an Anticoagulant, while in Japan Almost One-Third of Patients are Undertreated

Approximately 63% of Cancer Patients in China Experienced a Venous Thromboembolism within the First 6 Months of Diagnosis

Abelacimab is Already Being Studied in 23 Countries throughout North America, Europe, and Elsewhere in the Asia Pacific Region

CAMBRIDGE, Mass., June 8, 2023 – Anthos Therapeutics, a clinical-stage biotechnology company developing innovative therapies for cardiovascular

and metabolic diseases, today announced two important regulatory milestones in China and Japan for clinical trials of the company's investigational agent, abelacimab. Abelacimab is a novel, highly selective, dual-acting, fully human monoclonal antibody designed to induce effective hemostasis-sparing anticoagulation through Factor XI and Factor XIa inhibition.

In China, the National Medical Products Administration (NMPA) has granted approval for abelacimab to be studied in the ASTER and MAGNOLIA Phase 3 clinical trials which form the Cancer Associated Thrombosis clinical trial program for Anthos. Additionally, the Company received approval to initiate the Phase 3 LILAC-TIMI 76 trial investigating abelacimab in atrial fibrillation (AF) patients deemed unsuitable for current anticoagulants.

In Japan, the Pharmaceutical and Medical Device Authority (PMDA) also granted approval to initiate the Phase 3 LILAC-TIMI 76 trial investigating abelacimab in atrial fibrillation (AF) patients deemed unsuitable for current anticoagulants. Abelacimab is already being studied in Japan for patients with cancer associated thrombosis (CAT).

In non-valvular AF, more Chinese patients suffer a stroke than other racial and ethnic groups.[1] And yet a 2018 Chinese survey found that anticoagulants were prescribed to fewer than 26% of patients with non-valvular AF.[1] A separate, retrospective study exploring the impact of CAT concluded that 63% of cancer patients experienced a venous thromboembolism (VTE), a leading cause of death in patients with cancer, within the first 6 months of diagnosis.[2]

The prevalence rate of atrial fibrillation has increased by 33% globally during the last 20 years, resulting in approximately 38 million people worldwide burdened by its consequences.[3] The number of cases in Japan alone is expected to exceed 1 million.[4] Further, a Japanese registry reported that about one-third of AF patients were currently underdosed on anticoagulants.[2]

"The distressing evidence emerging from China and Japan clearly shows the global burden of atrial fibrillation and cancer associated thrombosis has no borders, and the need for more advanced therapies that can better address these mounting unmet needs is urgent," said Nik Mehta, Ph.D., Chief Technical and Regulatory Officer, Anthos Therapeutics. "The clinical trial approvals in China and Japan, add to the positive responses we've received from regulatory agencies around the world, including other countries in the Asia Pacific Region, such as Taiwan, South Korea, and Australia, where they are already enrolling patients in innovative clinical trials studying abelacimab."

“The vision of Anthos Therapeutics is to bring life-preserving therapies to disease areas underserved by current therapies. We strongly believe that our Factor XI/XIa program with abelacimab may do just that for a significant amount of atrial fibrillation patients deemed unsuitable for anticoagulants, as well as for cancer patients who present with an acute thrombotic event,” added Dan Bloomfield, Chief Medical Officer, Anthos Therapeutics. “It is highly encouraging to see that Factor XI inhibitors, as a class, have shown the potential to uncouple hemostasis from thrombosis. This represents a major paradigm shift in how patients could be treated in the future.”

In the U.S., abelacimab received its first Fast Track Designation from the FDA in July 2022 for the treatment of thrombosis associated with cancer. In September 2022, abelacimab was granted a second Fast Track Designation for the prevention of stroke and systemic embolism in patients with atrial fibrillation. Abelacimab is an investigational agent that has not been approved for any indication in any country.

About the LILAC-TIMI 76 Phase 3 Trial
The LILAC-TIMI 76 trial is an event-driven, randomized, placebo-controlled, double-blind, parallel-group study to evaluate the efficacy and safety of abelacimab relative to placebo on the rate of ischemic stroke or systemic embolism in patients with atrial fibrillation (AF) who have been deemed to be unsuitable for currently available anticoagulation therapy. Patients in the study will be randomized to receive abelacimab 150 mg SC or matching placebo once monthly. The study is targeting to enroll approximately 1900 patients from more than 300 sites in North America, Europe, Latin America, and Asia. Abelacimab received FDA Fast-Track designation for the prevention of stroke and systemic embolism in patients with atrial fibrillation in September 2022.

About the AZALEA-TIMI 71 Phase 2 Trial
The AZALEA-TIMI 71 trial is an event-driven, randomized, active-controlled, blinded endpoint, parallel-group study to evaluate the effect of two blinded doses of abelacimab relative to open-label rivaroxaban on the rate of major or clinically relevant non-major (CRNM) bleeding events in patients with atrial fibrillation (AF) who are at moderate-to-high risk of stroke. This event-driven trial completed enrollment in December 2021, with 1287 patients across 95 global study sites including the U.S. and Canada, as well as parts of Europe, and Asia remains ongoing.

About the Abelacimab Phase 3 Program in Cancer Associated Thrombosis (CAT)
The abelacimab Phase 3 CAT program comprises two complementary studies targeting to enroll approximately 2700 patients across 220 sites in more than

23 countries -- the largest program of any anticoagulant performed in cancer-associated thrombosis. Abelacimab received FDA Fast-Track designation for the treatment of thrombosis associated with cancer in July 2022.

MAGNOLIA is an international multicenter, randomized, open-label, blinded endpoint evaluation, Phase 3 study in patients with gastrointestinal (GI) / genitourinary (GU) cancer in whom DOAC treatment is not recommended. The study will compare the effect of abelacimab relative to dalteparin on VTE recurrence and bleeding in patients with cancer associated VTE who are at a high bleeding risk with non-resectable, locally or regionally invasive GI / GU tumors. Abelacimab 150 mg will be administered intravenously (IV) on Day 1 and subcutaneously (SC) monthly thereafter for up to 6 months; dalteparin administered subcutaneously will be given daily, 200 IU/kg/day for the first month, and then 150 IU/kg/day up to 6 months. Recruitment for this trial began in August 2022.

ASTER is an international multicenter, randomized, open-label, blinded endpoint evaluation, Phase 3 study comparing the effect of abelacimab relative to apixaban on venous thromboembolism (VTE) recurrence and bleeding in patients with cancer associated VTE in whom DOAC treatment is recommended. Abelacimab 150 mg will be administered intravenously (IV) on Day 1 and subcutaneously (SC) monthly thereafter for up to 6 months; Apixaban 10 mg will be administered orally, twice daily (bid) for the first 7 days, followed by 5 mg bid up to 6 months.

About Abelacimab

Abelacimab is a novel, highly selective, fully human monoclonal antibody designed to induce effective hemostasis-sparing anticoagulation through Factor XI inhibition. Abelacimab targets the active domain of Factor XI, demonstrating dual inhibitory activity against both Factor XI and its activated form, Factor XIa. By uncoupling thrombosis from hemostasis, factor XI inhibitors may provide a path forward for these patients to benefit from the protection that anticoagulants can provide. In patients with atrial fibrillation, abelacimab is planned to be dosed subcutaneously (SC) monthly to maintain nearly complete inhibition in a chronic setting. It is also planned to be administered via an initial intravenous (IV) infusion for acute indications requiring immediate onset of action and then followed by subsequent monthly SC administration. In a PK/PD study, abelacimab administered IV provided profound suppression of Factor XI within one hour after the start of therapy and maintained near maximal inhibition for up to 30 days.[5] In a Phase 2 study whose results were published in the New England Journal of Medicine in 2021, a single intravenous dose of abelacimab after knee surgery

reduced the rate of venous thromboembolism by 80%, measured 10 days after surgery, compared to enoxaparin.[6] Factor XI inhibition offers the promise of hemostasis-sparing anticoagulation for the prevention and treatment of arterial and venous thromboembolic events.[7]

About Anthos Therapeutics

Anthos Therapeutics is a clinical-stage biopharmaceutical company focused on the development and commercialization of genetically and pharmacologically validated innovative therapies to advance care for people living with cardiovascular and metabolic (CVM) diseases. Anthos Therapeutics aims to combine the agility of a biotech with the rigor of a large pharmaceutical company. Anthos Therapeutics was launched by Blackstone Life Sciences and Novartis in 2019 and has obtained the global rights to develop, manufacture, and commercialize abelacimab (MAA868) under a license agreement with Novartis. For more information, visit the company's website and follow on Twitter and LinkedIn.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding the initiation, and timing, of future clinical trials and its research and development. All statements, other than statements of historical facts, contained in this press release, including statements regarding the company's strategy, future operations, future financial position, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "become", "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. In addition, the forward-looking statements included in this press release represent the company's views as of the date hereof and should not be relied upon as representing the company's views as of any date subsequent to the date hereof. The company anticipates that subsequent events and developments will cause the company's views to change. However, while the company may elect to update these forward-looking statements at some point in the future, the company specifically disclaims any obligation to do so.

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