Abelacimab: First Factor XI Inhibitor to Enroll Patients in a Phase 3 Clinical Trial

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Abelacimab is a dual-acting fully human monoclonal antibody targeting both Factor XI and Factor XIa with high affinity and selectivity

Robust phase 3 clinical program includes two complementary trials *(ASTER and MAGNOLIA)* that will enroll ~2700 patients to study abelacimab in patients with Cancer Associated Thrombosis (CAT)

The ASTER study will compare abelacimab against the most widely prescribed Factor Xa agent

CAMBRIDGE, Mass., May 5, 2022 /PRNewswire/ -- Anthos Therapeutics, a clinical-stage biopharma company developing innovative therapies for cardiovascular and metabolic diseases, today announced that the first patient had been enrolled in a phase 3 clinical trial investigating a Factor XI agent. The ASTER study is one of two complementary, international, multicenter trials where abelacimab is being studied in patients with Cancer Associated Thrombosis (CAT). In the ASTER trial, Anthos' novel dual-acting Factor XI monoclonal antibody,

abelacimab, is being compared to apixaban, the leading Factor Xa inhibitor, to assess their effects on venous thromboembolism (VTE) recurrence and bleeding in patients with cancer associated VTE.

"Encouraged by evidence from a recently completed positive phase 2 study,[1] we believe abelacimab could become an important new treatment option for the treatment and prevention of thrombosis in a variety of patients, including those with Cancer Associated Thrombosis. Abelacimab's novel dual inhibitory activity offers the potential to provide effective antithrombotic activity with a reduced risk of bleeding compared to existing therapies. Additionally, the monthly dosing of abelacimab could reduce the burden of a daily regimen, such as daily injections or pills, for patients already receiving multiple therapies including chemotherapy," said Gary E. Raskob, Ph.D., Interim Senior Vice President, and Provost at the University of Oklahoma Health Sciences Center and the Chair of the Abelacimab CAT Program Steering Committee.

Venous Thromboembolism (VTE), which includes both deep vein thrombosis and pulmonary embolism, is the second most prevalent cause of death in patients with cancer, second only to the disease itself.[2] However, treatment of CAT can be challenging because the currently available anticoagulants used to treat VTE can have an increased risk of bleeding.[3,4]

"An acute episode of thrombosis in patients with cancer adds additional complexity to the treatment of cancer itself and is a grave concern for physicians, patients, and caregivers. Our extensive phase 3 program for abelacimab includes two trials specifically designed for patients with Cancer Associated Thrombosis, including those with a particularly high risk of bleeding. Enrolling the first patients in the ASTER phase 3 trial is an important first step toward making an effective and potentially safer anticoagulant available to patients with cancer. This phase 3 program is in addition to our ongoing phase 2 AZALEA-TIMI 71 trial comparing abelacimab to rivaroxaban in atrial fibrillation (AF), which completed enrollment with 1,287 patients in December 2021. This study, the largest trial to date with a Factor XI inhibitor, will compare bleeding rates in AF patients treated with abelacimab and rivaroxaban," said Dan Bloomfield, M.D., Chief Medical Officer, Anthos Therapeutics.

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. Abelacimab can be administered intravenously (IV) to achieve rapid inhibition of Factor XI activity and then used subcutaneously (SC) monthly to maintain nearly complete inhibition in a chronic setting. 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. [1,5] 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.[1] Factor XI inhibition offers the promise of hemostasis-sparing anticoagulation for the prevention and treatment of arterial and venous thromboembolic events.[6] Abelacimab is an investigational agent and has not been approved for any indication.

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 20 countries -- the largest program of any anticoagulant performed in Cancer-Associated Thrombosis.

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.

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.

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. The trial completed enrollment in December 2021, with 1287 patients across 95 global study sites including the U.S., Canada, as well as from parts of Europe, and Asia.

1. Verhamme P et al. *New Engl J Med July 2021* (https://www.nejm.org/doi/full/10.1056/NEJMoa2105872)
2. Fernandes CJ et al. *Eur. Resp. Rev. 2019* (https://err.ersjournals.com/content/28/151/180119)
3. Agnelli G et al. *New Engl J Med April 2020* (https://www.nejm.org/doi/full/10.1056/NEJMoa1915103)
4. Abdol Razak NB et al. *Cancers (Basel) Oct. 2018* (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6209883/)
5. Yi BA et al. *J Thromb Haemost. Oct. 2021* (https://pubmed.ncbi.nlm.nih.gov/34714969/)
6. Hsu et al. *J Am Coll Cardiol. Aug. 2021* (https://www.sciencedirect.com/science/article/abs/pii/S0735109721053213?via%3Dihub)

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 in 2019.

For more information visit the website at https://www.anthostherapeutics.com/, Twitter at https://twitter.com/Anthos_Tx, and LinkedIn at https://www.linkedin.com/company/anthos-therapeutics/.

Forward Looking Statements

This news 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, research and development, and regulatory authority submissions. All statements, other than statements of historical facts, contained in this news release, including statements regarding Anthos Therapeutics' 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 news release represent Anthos Therapeutics' views as of the date hereof and should not be relied upon as representing Anthos Therapeutics' views as of any date subsequent to the date hereof. Anthos Therapeutics anticipates that subsequent events and developments will cause Anthos Therapeutics' views to change. However, while Anthos Therapeutics may elect to update these forward-looking statements at some point in the future, Anthos specifically disclaims any obligation to do so.

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