Anthos Therapeutics Announces that Abelacimab has Received FDA Fast Track Designation for the Treatment of Thrombosis Associated with Cancer

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Anthos Therapeutics →
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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

Earlier this year abelacimab became the first-ever Factor XI inhibitor to begin enrolling patients in a Phase 3 trial *(The ASTER Study)*

The AZALEA-TIMI 71 trial in patients with atrial fibrillation (AF) also remains ongoing after having completed enrollment with 1,287 patients

CAMBRIDGE, Mass., July 11, 2022 /PRNewswire/ -- Anthos Therapeutics, a clinical-stage biotechnology company developing innovative therapies for cardiovascular and metabolic diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast

Track Designation to its investigational Factor XI inhibitor, abelacimab, for the treatment of thrombosis associated with cancer. The company will also be announcing this important milestone today at a session of the ongoing 2022 Congress of the International Society on Thrombosis and Haemostasis (ISTH) Congress in London, UK.

The Fast Track Designation process is designed to facilitate the development and expedite the review of treatments for serious medical conditions, thereby, addressing unmet medical needs. Drugs that are included in this program may be eligible for more frequent interactions with the FDA to discuss the development path, and if the program criteria are met, eligibility for a potential Rolling Review, Accelerated Approval, and Priority Review.

Venous Thromboembolism (VTE), including 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.[1] However, treatment of Cancer Associated Thrombosis (CAT) can be challenging because the currently available anticoagulants used to treat VTE can have an increased risk of bleeding.[2,3]

"We believe that abelacimab has the potential to provide patients with cancer associated thrombosis an enhanced safety profile and overall low risk of bleeding, without sacrificing any efficacy of currently available agents. This unmet need is particularly true in patients with gastrointestinal / genitourinary (GI/GU) cancers who are at an even higher risk of bleeding and can be further burdened by the inconvenience of daily injections," said Dan Bloomfield, Chief Medical Officer at Anthos Therapeutics. "Fast track designation by the FDA is a significant milestone for abelacimab and Anthos Therapeutics, but more importantly represents another hopeful step forward for patients. We look forward to working closely with the FDA on our clinical trial program to bring once-monthly abelacimab to patients in need."

"Caring for cancer patients is a delicate and complex process, requiring a fine balance between the risks and benefits of their anticoagulant treatments. Managing thrombosis episodes is of the utmost importance for physicians, patients, and their caregivers, as untreated blood clots or bleeding episodes associated with currently available anticoagulants, can have dire consequences," said Jean Marie Connors, M.D., Associate Professor of Hematology at Harvard Medical School. "The hemostasis sparing potential of FXI inhibitors, such as abelacimab, may represent an important treatment advance in how we manage patients moving forward."

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. Enrollment in this trial began in May 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.

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.

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. [4,5] 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.[4] 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.

1. Fernandes CJ et al. *Eur. Resp. Rev. 2019* (https://err.ersjournals.com/content/28/151/180119)
2. Agnelli G et al. *New Engl J Med April 2020* (https://www.nejm.org/doi/full/10.1056/NEJMoa1915103)
3. Abdol Razak NB et al. *Cancers (Basel) Oct. 2018* (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6209883/)
4. Verhamme P et al. *New Engl J Med July 2021* (https://www.nejm.org/doi/full/10.1056/NEJMoa2105872)
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 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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