Anthos Therapeutics Announces that Abelacimab Has Received FDA Fast Track Designation for the Prevention of Stroke and Systemic Embolism in Patients with Atrial Fibrillation

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Anthos Therapeutics →
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This is the second Fast Track designation issued by the FDA for abelacimab

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

CAMBRIDGE, Mass., Sept. 8, 2022--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 for the investigation of abelacimab for the prevention of stroke and systemic embolism in patients with atrial fibrillation (AF).

This represents the second Fast Track designation Anthos has received in less than two months, with the FDA also assigning this designation to abelacimab for cancer-associated thrombosis (CAT) in July 2022. Earlier this year, abelacimab also became the first-ever Factor XI inhibitor to begin enrolling patients in Phase 3 trials.

“Although there have been important advances in anticoagulation treatment in the last 60 years, there remains a need for new agents that protect patients from having a stroke while offering a lower risk of bleeding than currently available anticoagulants. This is especially true for the elderly, patients with renal or hepatic impairment, and those with a prior history of bleeding,” said Peter Kowey, MD, FACC, FHRS, FAHA, professor of Medicine and Clinical Pharmacology at Sidney Kimmel Medical College at Thomas Jefferson University and the William Wikoff Smith Chair in Cardiovascular Research at the Lankenau Heart Institute. “Factor XI inhibitors have the potential to uncouple the processes that lead to thrombosis from those that are involved in creating normal clots. By doing so, the hope is that this new class of anticoagulants will be at least as effective as current treatments – and have an enhanced safety profile. An alternative administration method and less frequent dosing will facilitate the care of patients who, for a variety of reasons, struggle with daily pill taking.”

“The blood clot patient community is actively monitoring the development of Factor XI inhibitors, such as abelacimab, and the role they may play for many patients today who are either not being treated with an anticoagulant or are

being undertreated due to a fear of potential bleeding, poor adherence or other complications," said Leslie Lake, volunteer president of the National Blood Clot Alliance. "We are hopeful these new generation Factor XI inhibitors will help to significantly improve patient outcomes and reduce the incidence of morbidity and mortality we still see too often."

"Real-world evidence has shown that adherence to current therapies is less than ideal for many patients, including those with atrial fibrillation and cancer associated thrombosis[i]. This non-adherence may be associated with an increased risk of stroke[ii]," said Dan Bloomfield, MD, FACC, FAHA, chief medical officer, Anthos Therapeutics. "With one in four people dying from thromboembolic events globally[iii], the need to do better is urgent. As a company, we remain highly committed to working closely with the FDA to bring once-monthly abelacimab to patients in need."

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.

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[iv,v]. 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[vi]. Abelacimab, an investigational agent that has not been approved for any indication, received FDA Fast Track designation for the treatment of thrombosis associated with cancer (July 2022) and prevention of stroke and systemic embolism in patients with atrial fibrillation (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. The 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.

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 direct oral anticoagulant (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 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 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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[i] Riaz I, Bayne H, Deng Y, et al. Presented at the 2022 American Society of Clinical Oncology Annual Meeting; Chicago, Illinois. https://meetings.asco.org/abstracts-presentations/206703

[ii] Ozaki AF, Choi AS, Le QT, Ko DT, Han JK, Park SS, Jackevicius CA. Circ Cardiovasc Qual Outcomes. 2020 https://pubmed.ncbi.nlm.nih.gov/32148102/

[iii] Wendelboe, AM, Raskob, GE, Circulation Research, 2016 (https://www.ahajournals.org/doi/10.1161/circresaha.115.306841)

[iv] Verhamme P et al. New Engl J Med July 2021 (https://www.nejm.org/doi/full/10.1056/NEJMoa2105872)

[v] Yi BA et al. *J Thromb Haemost. Oct. 2021* (https://pubmed.ncbi.nlm.nih.gov/34714969/)

[vi] Hsu et al. J Am Coll Cardiol. Aug. 2021 (https://www.sciencedirect.com/science/article/abs/pii/S0735109721053213?via%3Dihub)