Angion Announces Phase 1b Trial of ANG-3070 in Patients with Idiopathic Pulmonary Fibrosis

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-- The FDA has accepted an IND application supporting clinical development of ANG-3070 in IPF

-- Phase 1b trial to be initiated to gather tolerability, safety, and pharmacokinetic data in IPF patients

UNIONDALE, N.Y., May 16, 2022 (GLOBE NEWSWIRE) -- Angion Biomedica Corp. (NASDAQ:ANGN), a biopharmaceutical company focused on the discovery, development, and commercialization of novel small molecule therapeutics to address fibrotic diseases, today announced U.S. Food and Drug Administration's (FDA) acceptance of an Investigational New Drug (IND) application supporting the clinical development of ANG-3070 in idiopathic pulmonary fibrosis (IPF) and clearance to begin a Phase 1b study of ANG-3070 in patients with IPF.

ANG-3070 is an oral tyrosine kinase inhibitor targeting platelet-derived growth factor receptor alpha and beta (PDGFRα and PDGFRβ, respectively) and Discoidin Domain Receptors 1 and 2 (DDR1 and DDR2), tyrosine kinase receptors linked to the development of fibrosis in the kidneys and lungs.

The Phase 1b study is intended to start enrollment and report data in 2022. IPF patients eligible for this Phase 1b study of ANG-3070 include those who have discontinued nintedanib or pirfenidone, refused treatment with nintedanib or pirfenidone, or those who are treatment naïve. Approximately 20 IPF patients will be enrolled into a crossover design trial with four arms dosing for ten days each. One arm is ANG-3070 300mg twice per day, the second arm is 500mg once per day, plus placebo-to-match arms. Patients will be enrolled in two ten-day treatment periods with either ANG-3070 or placebo with a 5 day of washout period between treatments. The primary endpoint of the study is the frequency of treatment-emergent adverse events. Secondary endpoints include standard pharmacokinetic analyses.

"The acceptance of this IND for ANG-3070 in patients with IPF is an important milestone for Angion," stated Dr. John Neylan, Angion's Executive Vice President and Chief Medical Officer. "The results from this study will assist us in designing and enrolling a Phase 2 trial in IPF, which we expect to initiate in 2023. IPF is a serious and ultimately fatal fibrotic disease where additional treatment options are needed."

Additionally, Angion has completed multiple preclinical studies demonstrating ANG-3070's activity in IPF models. These studies include:

- An *in vitro* study exploring ANG-3070's ability to inhibit proliferation of normal human lung fibroblasts, key components of the fibrotic pathway in IPF. ANG-3070 successfully inhibited fibroblast proliferation in the presence of PDGF, an important confirmation of ANG-3070's ability to inhibit a known component of IPF pathophysiology.
- An *in vitro* study of ANG-3070's ability to affect PDGF-mediated collagen secretion by normal human lung fibroblasts. Collagen secretion is part of the final pathway contributing to the pathology of fibrotic lung tissue in IPF and other progressive fibrotic diseases. ANG-3070 abrogated collagen secretion in this model, demonstrating activity against this pathway of progressive IPF.
- An *in vitro* study exposing ANG-3070 to normal human fibroblasts and human small airway epithelial cells, the latter cells being critical to healthy lung function. The ability of ANG-3070 to effectively inhibit fibroblast activation and collagen secretion while sparing small airway epithelial cells in this model suggests potentially increased clinical benefit via protection of the small airway epithelial cells and the alveolar epithelium from further damage.

"These *in vitro* studies provide further demonstration of ANG-3070's potential for clinical activity in IPF," continued Dr. Neylan. "These data complement the significant body of existing *in vivo* studies showing activity of ANG-3070 in both kidney and lung fibrosis, enabling us to advance a robust clinical development program for ANG-3070 in both primary proteinuric kidney diseases in our Phase 2 JUNIPER trial as well as in IPF."

IPF is an aggressive form of fibrotic lung disease with a median survival for patients between two and three years. Approximately 140,000 patients in the U.S. have been diagnosed with IPF. While both nintedanib and pirfenidone are approved in the U.S. for IPF, approximately half of IPF patients discontinue their prescriptions within one year and fewer than one-third of IPF patients are currently prescribed either drug. Nevertheless, worldwide sales for nintedanib and pirfenidone are projected to be over $3.8 billion in 2021.

About ANG-3070
ANG-3070 is a highly selective oral tyrosine kinase receptor inhibitor in development as a treatment for fibrotic diseases, particularly in the kidney and lung. ANG-3070 has demonstrated activity as an anti-fibrotic agent in a variety of animal models. A Phase 1 healthy volunteer study demonstrated ANG-3070 to have a favorable safety and PK profile, producing plasma concentrations which exceeded those demonstrating activity in animal models of proteinuric kidney diseases. Enrollment is ongoing in JUNIPER, a dose-finding Phase 2 trial of ANG-3070 in primary proteinuric kidney diseases (NCT04939116). A Phase 1b trial of ANG-3070 in patients with idiopathic pulmonary fibrosis is targeted to enroll and report data in 2022.

About Angion
Angion is committed to transforming the treatment paradigm for patients suffering from fibrotic diseases for which there are no approved medicines or where existing approved medicines have known limitations. Angion's lead product candidate is ANG-3070, a highly-selective oral tyrosine kinase receptor inhibitor in development for the treatment of fibrotic kidney and lung diseases. Enrollment is ongoing in JUNIPER, a dose-finding Phase 2 trial of ANG-3070 in primary proteinuric kidney diseases (NCT04939116). A Phase 1b trial of ANG-3070 in patients with idiopathic pulmonary fibrosis is targeted to enroll and report data in 2022. Additionally, Angion has preclinical programs focused on a rho kinase 2 (ROCK2) inhibitor and a CYP11B2 (aldosterone synthase) inhibitor. For more information, please visit www.angion.com.

Forward Looking Statements

Statements contained in this press release regarding matters that may occur in the future are “forward looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to statements in this press release regarding the potential of ANG-3070 as a treatment for primary proteinuric kidney diseases and as a treatment for IPF, the timing of enrollment of the global Phase 2 trial of ANG-3070 in patients with IPF, and Angion’s expectations to enroll and report data in 2022 from the Phase 1b trial of ANG-3070 in patients with IPF. Such statements are subject to risks and uncertainties and actual results may differ materially from those expressed or implied by such forward-looking statements. In particular, the following factors, among others, could cause results to differ materially from those expressed or implied by such forward-looking statements: Angion’s ability to demonstrate sufficient evidence of efficacy and safety in its clinical trials of ANG-3070 and its other product candidates; the accuracy of Angion’s estimates relating to its ability to initiate and/or complete clinical trials; the results of preclinical studies may not be predictive of future results; the costs of clinical trials may exceed expectations; Angion’s ability to raise additional capital; and the effects of COVID-19 on Angion’s clinical programs and business operations. For a description of risks and uncertainties that could cause actual results to differ from those expressed in forward-looking statements, see Angion’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the Securities and Exchange Commission on May 16, 2022, especially under the caption “Risk Factors,” as well as other documents that may be filed by Angion from time to time with the Securities and Exchange Commission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Angion undertakes no obligation to update any forward-looking statement in this press release, except as required by law.

Contact David D. Miller Sr. Director of Corporate Affairs investors@angion.com