Angion Reports Positive Results from Phase 1 Healthy Volunteer Study for ANG-3070 and FDA Authorization to Initiate Phase 2 Trial in 2021

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- *ANG-3070 was well-tolerated across dose cohorts, achieving drug exposures in humans exceeding exposures in which activity was demonstrated in animal models of proteinuric kidney diseases*
- *Pharmacokinetic data potentially supportive of once-daily dosing*
- *An international Phase 2 trial in patients with primary proteinuric kidney diseases will begin enrolling patients in the second half of this year*
- *Company to host a Virtual Fibrosis R&D Day on September 20, 2021*

UNIONDALE, N.Y., Aug. 03, 2021 (GLOBE NEWSWIRE) -- Angion Biomedica Corp (NASDAQ:ANGN), a late-stage biopharmaceutical company focused on the discovery, development, and commercialization of novel small molecule therapeutics to address acute organ injuries and fibrotic diseases, today announced positive results from its Phase 1 study in healthy volunteers for ANG-3070, a novel oral tyrosine kinase receptor inhibitor (TKI) being developed for the treatment of fibrotic diseases. Angion also announced the FDA's acceptance of an IND application supporting the initiation of a Phase 2 trial in patients with primary proteinuric kidney diseases in 2021. Additionally, the Company announced it will host a Virtual Fibrosis R&D Day on September 20, 2021.

Key findings from the ANG-3070 Phase 1 healthy volunteer study included:

- ANG-3070 achieved drug exposures in humans exceeding exposures in which activity was demonstrated in animal models of proteinuric kidney diseases
- ANG-3070 demonstrated a favorable safety and tolerability profile, including with respect to gastrointestinal side effects, which was encouraging given the well-recognized incidence and severity of these side effects in approved TKIs
- Pharmacokinetic data supportive of potential once-daily oral dosing for ANG-3070

The Phase 1 study was a randomized, double-blind, and placebo-controlled study in healthy volunteers conducted in Australia to assess the safety, tolerability, pharmacokinetics, and food effect of ANG-3070 dosed orally. The study consisted of both single-and multiple-ascending dose cohorts and enrolled 97 healthy volunteers, with 72 volunteers receiving ANG-3070 and 25 volunteers receiving placebo. Doses studied in the study ranged from 50mg to 600mg and included both once daily and twice daily regimens.

"We are very pleased with the results from the Phase 1 healthy volunteer study of ANG-3070," said John F. Neylan, M.D., Angion's Chief Medical Officer. "The data from this study surpassed expectations, where ANG-3070 exposures seen in the study exceeded the levels of drug exposure needed to demonstrate activity in our animal models of kidney disease. The favorable safety and PK profile seen in the study allows us the flexibility to use a range of dose levels as we explore the efficacy of ANG-3070 in a Phase 2 trial in patients with primary proteinuric kidney diseases."

ANG-3070 demonstrated a favorable safety and tolerability profile in the study. There were no serious adverse events reported at any dose schedule or level. The reported (non-serious) adverse events were seen mostly at higher doses, 600 mg administered once-daily and 500 mg administered twice-daily over two weeks. These adverse events included nausea, abdominal cramps, and diarrhea, and were considered mild to moderate in severity. This was encouraging given the well-recognized incidence and severity of these side effects in approved TKIs.

The international Phase 2 clinical trial of ANG-3070 will be a randomized, double-blind, and placebo-controlled study of ANG-3070 in approximately 100 patients with primary proteinuric kidney diseases, including IgA nephropathy and focal segmental glomerulosclerosis (FSGS). The study will investigate three dose levels of ANG-3070, 200mg and 400mg once a day and 300mg twice a day, compared to placebo. The primary endpoint of the study is the percentage change in 24-hour urinary protein excretion at the end of 12 weeks of dosing. This exploratory Phase 2 trial is expected to enroll its first patient in the second half of this year.

Virtual Fibrosis R&D Day
The Company also announced it will host a Virtual Fibrosis R&D Day on September 20, 2021, at 10am US Eastern Daylight Time via a live online webcast. During the event, the Company will cover the potential of ANG-3070 for the treatment of kidney and lung fibrosis and provide additional data from preclinical studies of ANG-3070.

About ANG-3070
ANG-3070 is a highly selective, orally-bioavailable small molecule tyrosine kinase receptor inhibitor developed as a treatment for fibrotic diseases, particularly in the lung and kidney. ANG-3070 has demonstrated activity as an anti-fibrotic agent in a variety of animal models in the kidney, lungs, and gastrointestinal system. A Phase 1 healthy volunteer study demonstrated ANG-3070 to have a favorable safety and PK profile, producing drug exposures which exceeded those demonstrating activity in animal models of proteinuric kidney diseases. The first patient in an exploratory Phase 2 trial of ANG-3070 in primary proteinuric kidney diseases is expected to be enrolled in the second half of this year.

About Angion
Angion is committed to transforming the treatment paradigm for patients suffering from acute organ injuries and fibrotic diseases for which there are no approved medicines or where existing approved medicines have limitations. Angion's lead product candidate, ANG-3777, is a hepatocyte growth

factor (HGF) mimetic currently being evaluated in a Phase 3 registration trial for delayed graft function in patients undergoing deceased donor kidney transplantation and a Phase 2 trial in cardiac-surgery associated acute kidney injury. Angion is scheduled to begin a Phase 2 trial evaluating ANG-3070, an oral tyrosine kinase receptor inhibitor for the treatment of fibrotic disease, in patients with primary proteinuric kidney diseases. Additionally, Angion has preclinical programs for 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 Angion’s expectations regarding the potential safety and efficacy of ANG-3070 in fibrotic diseases, such as primary proteinuric kidney diseases, the potential results and outcomes of our clinical development program involving ANG-3070, and the timing of the initiation of the ANG-3070 Phase 2 study. 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-3777, ANG-3070, and its other product candidates; the accuracy of the Company’s estimates relating to its ability to initiate and/or complete clinical trials; the results of preclinical studies to be predictive of future results; the unpredictability of the regulatory process; regulatory developments in the United States, and other foreign countries; the costs of clinical trials may exceed expectations; the Company’s ability to raise additional capital; the effects of COVID-19 on the Company’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 the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed with the Securities and Exchange Commission on May 17, 2021, as well as other documents that may be filed by the Company 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.

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