Angion Announces Results from the Phase 2 ALI-201 Study in Patients with COVID-19 Associated Pneumonia

June 29, 2021

UNIONDALE, N.Y., June 29, 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 that its exploratory Phase 2 ALI-201 trial of ANG-3777 in patients with severe COVID-19 related pneumonia at high risk for acute respiratory distress syndrome (ARDS) did not meet the primary or secondary efficacy endpoints. The adverse events and overall safety of the trial were consistent with previously published reports in patients hospitalized with severe COVID-19 pneumonia.

“The ALI-201 study sought to address a patient population severely ill with COVID-19, a multi-system inflammatory condition, which differs markedly from our prior and ongoing clinical trials of ANG-3777 related to transplantation and cardiovascular surgery where the acute kidney injury is a discrete event,” stated Dr. John F. Neylan, Angion’s Chief Medical Officer. “Patients in the ALI-201 trial had ongoing and accumulating injury from symptomatic COVID-19 on average 11 days before receiving drug with organ systems under continued attack from the SARS-CoV-2 virus. In contrast, patients in our ongoing trials receive ANG-3777 within 1-3 days after the targeted organ injury. COVID-19 is a severe systemic disease presenting significant challenges to both new and previously approved therapeutics.”

“We were pleased to be part of the attempt to help patients severely ill with COVID-19 and extend our deepest gratitude to the patients, their families, investigators, and site staff who participated in this study,” commented Dr. Jay R. Venkatesan, Angion’s President and Chief Executive Officer. “With the increasing availability of approved COVID-19 vaccines and the widespread assumption vaccines will reduce infection rates around the world, we will not continue the development of this COVID-19 program. Based on the promising activity of ANG-3777 in multiple animal models of lung injury, we will continue to evaluate the clinical development of ANG-3777 for acute lung injury populations.”

The ALI-201 study was a small exploratory Phase 2 double-blind, randomized, and placebo-controlled trial conducted in Brazil to evaluate the safety and efficacy of four doses of ANG-3777 in the reduction of severity and progression of acute lung injury in patients with COVID-19 associated pneumonia who are at high risk of progressing to ARDS. The primary endpoint of the trial was survival free from the need for mechanical ventilation or dialysis at 28 days. The active arm of the trial did not show a statistically significant difference over the standard of care arm. A total of 120 patients were randomized 1:1 in the trial, with 59 patients in the active treatment arm and 61 patients in the standard of care arm.

The number of adverse events, serious adverse events, and fatal events reported in ALI-201 were slightly higher for those subjects in the active treatment arm compared to those in the standard of care control arm, although no new or unexpected safety signals resulted from the trial. None of the fatal events in this trial of advanced COVID-19 patients were attributed by study investigators to either ANG-3777 or standard of care in the control arm.

The company expects to report data from the ANG-3777 Phase 3 registration trial in transplant-associated acute kidney injury, also known as delayed graft function, by the end of 2021. The company also expects to report data from the ANG-3777 Phase 2 proof of-concept trial for the treatment of acute kidney injury associated with cardiac surgery involving cardiopulmonary bypass surgery in the second half of 2021.

About ANG-3777
ANG-3777 is a small molecule designed to mimic the biological activity of hepatocyte growth factor (HGF), which activates the c-Met cascade of pathways involved in tissue repair and organ repair. ANG-3777 has a substantially longer half-life than HGF and Angion believes ANG-3777 has the potential to be a first-in-class therapeutic addressing acute organ injury. The ongoing clinical trials of ANG-3777 include a placebo-controlled Phase 3 registration trial in transplant-associated acute kidney injury, also known as delayed graft function and a Phase 2 proof of-concept trial for the treatment of acute kidney injury associated with cardiac surgery involving cardiopulmonary bypass surgery. In November 2020, Vifor Pharma and Angion signed a license agreement worth up to $1.9 billion in development, commercial, and sales milestones plus royalties on net sales of up to 40% for global rights outside Greater China to commercialize ANG-3777 in nephrology indications. Sinovant Sciences and Angion signed a development and licensing agreement for ANG-3777 in Greater China in 2018.

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 evaluating 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 also currently evaluating ANG-3070, a tyrosine kinase receptor inhibitor for the treatment of fibrotic disease, in Phase 1. 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-3777 and the timing of the availability of and Angion’s disclosure of topline data from such studies. 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 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 may

not be predictive of future results; the unpredictability of the regulatory process; and regulatory developments in the United States, and other foreign countries. 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, particularly under the caption "Risk Factors," as well as other documents filed from time to time by the Company 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 Daniel Ferry LifeSci Advisors 617-430-7576 daniel@lifesciadvisors.com