



## Angion and Vifor Pharma Announce Completion of Enrollment in Phase 2 Study of ANG-3777 for Cardiac-Surgery Associated Acute Kidney Injury

April 29, 2021

### Topline data expected in the second half of 2021

UNIONDALE, N.Y. and ST. GALLEN, Switzerland, April 29, 2021 (GLOBE NEWSWIRE) -- Angion Biomedica Corp (NASDAQ:ANGN) and Vifor Pharma today announced completion of enrollment for Angion's AKI-002-15 study, a Phase 2 trial of ANG-3777 in patients at risk of cardiac-surgery associated acute kidney injury (CSA-AKI). This indication is part of the ANG-3777 license agreement both parties signed in November 2020.

"CSA-AKI is a frequent complication of cardiac bypass surgery seen in about one third of patients and is associated with prolonged hospitalization, progressive kidney failure, and an increased risk of death," commented Dr. John Neylan, Angion's Senior Vice President and Chief Medical Officer. "Currently, there are no approved therapies to prevent this serious condition. This Phase 2 prevention trial was designed to generate data on ANG-3777 in CSA-AKI patients to help guide future development of ANG-3777 in a Phase 3 registration trial for CSA-AKI. We are planning to start the confirmatory trial early in 2022, subject to the results of this Phase 2 trial as well as discussions with the FDA and other relevant health authorities."

Dr. Klaus Henning Jensen, Chief Medical Officer of Vifor Pharma Group commented: "We are excited that enrollment in the AKI-002-15 Phase 2 trial has completed. This is an important milestone in a comprehensive clinical program to advance ANG-3777 as a potential treatment option to prevent acute kidney injury following cardiac surgery, an indication with a high unmet medical need. Together with our partner Angion, we now look forward to assessing the results from the trial."

The fully enrolled Phase 2 trial is a randomized, multi-center, double-blind, placebo-controlled clinical trial with trial sites in the United States, Canada, Brazil, and Georgia. Patients at risk for CSA-AKI were randomized one-to-one to receive four intravenous doses of 2.0 mg/kg of ANG-3777 or placebo over four days. The first dose was given within four hours of the completion of surgery with subsequent doses given at 24-hour intervals. The primary endpoint is mean area under the curve of the percent increase in serum creatinine above baseline, starting from 24 hours after the end of cardiopulmonary bypass surgery through day six. An additional important endpoint is the occurrence of Major Adverse Kidney Events at 90 days (MAKE 90), which has previously been agreed by the FDA as a suitable primary endpoint for a registration trial in this indication. A MAKE 90 "event" is death, initiation of renal replacement therapy or a greater than 25% decline in eGFR present 90 days after the surgery. The AKI-002-15 Phase 2 trial was designed as a signal-finding trial with the strategic objective to obtain sufficient evidence of efficacy of ANG-3777 to appropriately power and evaluate potential enrichment strategies for a Phase 3 registration trial.

### About ANG-3777

ANG-3777 is an investigational small molecule designed to mimic the biological activity of hepatocyte growth factor (HGF), which activates the c-Met cascade of pathways involved in tissue and organ repair. ANG-3777 has demonstrated 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. Enrollment is complete in a Phase 3 registration trial in transplant-associated acute kidney injury, also known as delayed graft function, a Phase 2 exploratory trial in cardiac-surgery associated acute kidney injury, and a Phase 2 exploratory trial in patients with acute lung injury associated with COVID-19 pneumonia. In November 2020, Vifor Pharma and Angion signed a license agreement for global rights excluding Greater China to commercialize ANG-3777 in renal indications with up to \$1.925 billion in development, commercial, and sales milestones plus royalties on net sales of up to 40%. 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, a Phase 2 trial in cardiac-surgery associated acute kidney injury, and a Phase 2 trial in patients with COVID-19 related pneumonia at high risk for acute respiratory distress syndrome. 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](http://www.angion.com).

### About Vifor Pharma Group

Vifor Pharma Group is a global pharmaceutical company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care). Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348). For more information, please visit [viforpharma.com](http://viforpharma.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, the potential results and outcomes of the AKI-002-15 study, and other studies involving ANG-3777 or other product candidates, the timing of the commencement of future clinical trials and the timing of 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; 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 Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission on March 30, 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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