



Angion and Vifor Pharma Report Topline Results from Phase 3 Trial of ANG-3777 in Kidney Transplant Patients at Risk for Delayed Graft Function

October 26, 2021

Angion to host a conference call at 4:30 p.m. EDT

UNIONDALE, N.Y. and ST. GALLEN, Switzerland, Oct. 26, 2021 (GLOBE NEWSWIRE) -- Angion Biomedica Corp. (NASDAQ:ANGN) and Vifor Pharma today announced the Phase 3 trial of Angion's ANG-3777 did not demonstrate a statistically significant difference from placebo on the primary endpoint (eGFR at 12 months) in the population of deceased donor kidney transplant patients who were at risk for developing delayed graft function (DGF).

ANG-3777 showed a modest but not statistically significant difference in eGFR of 53.3mL/min/1.73m² versus 50.4mL/min/1.73m² for placebo (2.9 mL/min/1.73m², p=0.33). In addition, ANG-3777 demonstrated an inconsistent benefit on key secondary endpoints. Based upon these data, it is not expected there is sufficient evidence to support an indication in the studied DGF population.

The statistical analysis plan also included an analysis of only those people who completed the trial, without using a multiple imputation method to account for missing data and intercurrent events. Under this analysis, ANG-3777 showed a difference on 12-month eGFR of 57.1mL/min/1.73m² versus 52.2mL/min/1.73m² (4.9mL/min/1.73m², p=0.06) for placebo. These data are potentially indicative of biologic activity of ANG-3777.

The overall safety profile of ANG-3777 in this trial was consistent with the overall experience in its clinical development program and consistent with the published literature in this patient population.

"We are disappointed in the outcome of this trial. While we saw signals of activity for ANG-3777, we hoped ANG-3777 would robustly demonstrate a benefit for transplant recipients who have no treatment options when their transplants have DGF," stated Jay Venkatesan, M.D., Angion's President and CEO. "The totality of the DGF data, together with the CSA-AKI data expected later this year, will inform our clinical strategy with respect to ANG-3777 going forward. I want to extend my special thanks to the patients, their families, and the investigators and their staff members who participated and worked diligently on this trial."

"Unfortunately, the results of the Phase 3 registrational trial did not confirm as strong of an effect as we hoped for in the interests of patients experiencing DGF after kidney transplantation," said Dr. Klaus Henning Jensen, Chief Medical Officer of Vifor Pharma. "These kinds of challenges are part of clinical development activities. Our collaboration with Angion and the development of ANG-3777 in cardiac-surgery associated acute kidney injury continues unchanged, with topline data expected later this year."

This multi-center, double-blinded, and placebo-controlled Phase 3 trial randomized 253 patients 1:1 to receive ANG-3777 or a placebo treatment dosed once per day for three days. Eligible patients received a deceased donor transplant and were determined to be at risk for delayed graft function by having low urine output (oliguria) for more than 8 consecutive hours post-transplant, reflecting potential graft injury. Twenty-five transplant centers in the U.S. enrolled patients in this Phase 3 registration trial. The primary endpoint was renal function assessed by estimated glomerular filtration rate (eGFR) with a primary analysis time point of eGFR at twelve months using a pre-specified multiple imputation method.

Angion expects to report cash and cash equivalents as of September 30, 2021 totaling approximately \$100 million, when it reports quarterly earnings in November 2021.

Conference Call

The Angion management team will host a conference call today at 4:30 p.m. EDT to discuss the topline data. The dial-in number for the conference call is 1-877-407-0792 for domestic participants and 1-201-689-8263 for international participants, with Conference ID #13724738. A live webcast of the conference call can be accessed at the "Events & Presentations" page on the Angion website at <https://ir.angion.com/events-presentations>. A replay will be available on this website shortly after conclusion of the event.

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. An exploratory Phase 2 trial for the treatment of acute kidney injury associated with cardiac surgery involving cardiopulmonary bypass (CSA-AKI) is ongoing with data expected in the fourth quarter of 2021. In November 2020, Vifor Pharma and Angion signed a license agreement for global rights outside Greater China to commercialize ANG-3777 in nephrology indications only.

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. An exploratory Phase 2 trial of ANG-3777 for the treatment of acute kidney injury associated with cardiac surgery involving cardiopulmonary bypass surgery is ongoing with data expected in the fourth quarter of 2021. 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.

About Vifor Pharma Group

Vifor Pharma Group is a global pharmaceuticals 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.

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 that release of topline data from the ANG-3777 Phase 2 exploratory trial for the treatment of acute kidney injury associated with cardiac surgery involving cardiopulmonary bypass surgery will be in the fourth quarter of 2021, a global Phase 2 trial of ANG-3070 in patients with primary proteinuric kidney diseases will begin enrolling patients this year, and Angion expects to report cash and cash equivalents as of September 30, 2021 totaling approximately \$100 million. 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: reporting of trial results or commencing enrollment in clinical trials could be delayed for reasons outside of Angion’s control, including the effects of COVID-19 on Angion’s clinical programs and business operations; and Angion’s September 30, 2021 estimated cash is preliminary and is subject to review and adjustment during the financial review process. 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 June 30, 2021, filed with the Securities and Exchange Commission on August 12, 2021, particularly the information 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.

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