



Press  
Release

# Vifor Pharma and Angion report topline results from phase-II GUARD trial of ANG-3777 in cardiac surgery associated acute kidney injury

**St. Gallen, Switzerland, and Uniondale, NY, – 10 December 2021** – Vifor Pharma and Angion Biomedica Corp. (NASDAQ: ANGN) today announced results from the exploratory phase-II GUARD trial of Angion's ANG-3777 in patients undergoing cardiac surgery involving cardiopulmonary bypass at risk for developing acute kidney injury (CSA-AKI). The trial did not meet its primary endpoint of percentage increase in serum creatinine based upon the area under the curve (AUC). However, Angion and Vifor Pharma continue to review the data, based on the signal demonstrated in the clinically-relevant MAKE90 secondary endpoint.

The GUARD trial was designed as a signal-finding trial with a primary objective determining the feasibility of advancing ANG-3777 into a global phase-III trial based upon activity and safety of ANG-3777 in patients at risk for CSA-AKI, as there are no approved therapies for these patients.

Topline results appear below. P-values noted were not adjusted for multiple comparisons:

- The primary endpoint was percentage increase in serum creatinine based upon AUC as measured between 24 hours after the end of surgery through day 6, and indicated there was no significant difference in this short-term endpoint between ANG-3777 and placebo (8.4% vs. 7.3%,  $p=0.77$ ).
- The secondary endpoint of MAKE90, which has historically been acceptable to global regulatory agencies as an approvable endpoint, indicated a potential benefit in patients receiving ANG-3777 with fewer patients in the ANG-3777 arm having a MAKE90 event compared to those in the placebo arm (14.7% vs. 21.5%, adjusted odds ratio of 0.60,  $p=0.155$ ). MAKE90 is a composite endpoint combining death, initiation of renal replacement therapy, or a greater than 25% decline in Estimated Glomerular Filtration Rate (eGFR) present 90 days after the surgery. The GUARD trial was not powered to demonstrate a statistically significant result on this endpoint.
- The number of patients who experienced a decline in kidney function as measured by a  $\geq 25\%$  decrease in eGFR at Day 90 was fewer in the group treated with ANG-3777 (5.6% vs. 16.2%,  $p=0.012$ ). Other secondary endpoints did not show a clinical benefit, including endpoints on MAKE30 and the incidence of AKI through Day 6.

The overall safety profile of ANG-3777 in this trial was consistent with the overall experience in its clinical development program and comparable to placebo.

"With the results of this trial, we now have a body of data on the efficacy and safety of ANG-3777 in both transplant and surgery-associated kidney injury," said Dr. Klaus Henning Jensen, Chief Medical Officer of Vifor Pharma.

"Together with our partner Angion, we look forward to thoroughly analyze the full data set and to continue exploring the potential of ANG-3777."

"This is a preliminary data picture from the trial, and we need additional time to analyze the full data set before determining how we might bring ANG-3777 to patients," stated John Neylan, MD, Angion's Chief Medical Officer. "I would like to thank the patients, their families, and the investigators and their staff members who participated and worked diligently to make this trial possible."

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#### **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](http://viforpharma.com).

#### **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 ANG-3777 is a hepatocyte growth factor (HGF) mimetic. Angion and Vifor Pharma are evaluating the full data set from the Phase 2 GUARD trial in patients at risk for acute kidney injury associated with cardiac surgery involving cardiopulmonary bypass (CSA-AKI). Angion is evaluating ANG-3070, a highly-selective, orally-bioavailable tyrosine kinase receptor inhibitor in development for the treatment of fibrotic kidney and lung diseases and currently enrolling an exploratory Phase 2 trial 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](http://www.angion.com).

#### **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. Angion and Vifor Pharma are evaluating the full data set from the phase-II GUARD trial in patients at risk for acute kidney injury associated with cardiac surgery involving cardiopulmonary bypass (CSA-AKI). In November 2020, Vifor Pharma and Angion signed a \$1.8 billion total potential value license agreement for global rights outside Greater China to commercialize ANG-3777 in nephrology indications only.

#### **About the GUARD phase-II study**

In the GUARD (Guard Against Renal Damage) trial, a total of 275 patients were randomized 1:1 to receive four doses of ANG-3777 or placebo < 4 hours after the completion of cardiac surgery. Patients eligible for the GUARD trial were determined to be at risk for acute kidney injury based upon multiple factors, including age, baseline renal function, and complexity of the surgical procedure. Thirty-one centers in the U.S., Canada, Brazil, and Georgia participated in this exploratory phase-II trial. The primary endpoint was mean AUC of the percent increase in serum creatinine above baseline, starting from 24 hours after the end of cardiopulmonary bypass surgery through Day 6. MAKE90 is a composite endpoint combining death, initiation of renal replacement therapy, or a greater than 25% decline in eGFR. eGFR decline by >25% assessed at 90 days was calculated using the CKD-EPI formula.

#### **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 future analyses of the 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, the potential for a Phase 3 study of ANG-3777 in CSA-AKI, and the the expectation that global Phase 2 trial of ANG-3070 in patients with primary proteinuric kidney diseases will begin enrolling patients this year. 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: analysis 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. For a description of additional risks and uncertainties, see Angion's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed with the Securities and Exchange Commission on November 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.