Angion Biomedica Corp. To Commence Phase 2 Clinical Trial of BB3 in Acute Kidney Injury

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UNIONDALE, N.Y.--(BUSINESS WIRE)--Angion Biomedica Corp. announced today that the FDA issued a clearance letter allowing the Company to begin its Phase 2 “GUARD” clinical trial (GUard Against Renal Damage) using investigational drug BB3 in patients at risk for acute kidney injury (AKI). Angion discovered and has been developing BB3, which is a proprietary small molecule that mimics the activity of hepatocyte growth factor (HGF). BB3 has demonstrated organ protective and regenerative therapeutic effects in preclinical models of AKI.

AKI is one of the most serious and frequent in-hospital complications and is associated with increased mortality, need for dialysis, longer length of hospital stay, an increased risk of infection, an increased incidence of chronic kidney disease, and therefore, increased costs to health systems. There is currently no FDA approved drug therapy for the prevention or treatment of AKI.

Patients who undergo cardiac surgery involving use of cardiopulmonary bypass, also known as a heart-lung machine, in combination with predisposing factors, are at increased risk for AKI. The GUARD study is designed to evaluate the potential of BB3 to treat AKI in patients who undergo open heart surgery and require the use of cardiopulmonary bypass. GUARD is a multicenter, randomized, placebo-controlled, double-blind study involving approximately 100 patients in the U.S. that have risk factors for AKI including existing kidney disease, previous cardiac surgery, compromised heart function, advanced age, and diabetes.

“We are pleased to receive FDA clearance to evaluate BB3 in patients at high risk for acute kidney injury,” said Itzhak D. Goldberg, MD, FACR, President and CEO of Angion. “The GUARD study complements our Phase 3 study on BB3 in renal transplant patients presenting with delayed graft function, another form of AKI.”

"The evaluation of BB3 to treat patients at risk for AKI, and Angion's additional Phase 3 clinical trial of BB3 to treat delayed graft function in renal transplant patients, are both very exciting,” said Matthew R. Weir, M.D., Professor of Medicine and Head of the Division of Nephrology at the University of Maryland School of Medicine. “Should BB3 prove effective for preventing or treating AKI, it will represent a major breakthrough in the field of nephrology.”

About Angion Biomedica Corp.

Angion Biomedica Corp. is a biopharmaceutical company established in 1998 to discover and develop novel therapeutic agents to treat patients who experience acute and chronic organ disorders and diseases. Our programs are currently focused on renal transplantation, acute kidney injury and chronic kidney disease. Angion retains worldwide rights to BB3. For further information, please visit www.angion.com, or contact us at mail@angion.com.

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