



Angion Biomedica Corp. Advances BB3 into Pivotal Phase 3 Clinical Trial in Renal Transplant Patients with Delayed Graft Function

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UNIONDALE, N.Y.--(BUSINESS WIRE)--Angion Biomedica Corp. announced today that it plans to commence enrollment of a Phase 3 clinical trial using its investigational drug BB3 to treat delayed graft function (DGF) in kidney transplant recipients. This Phase 3 “GIFT” (Graft Improvement Following Transplantation) trial is a 152-patient, randomized, double-blind, placebo-controlled, multicenter clinical trial.

Delayed graft function is typically associated with transplant patients who receive sub-optimal, cadaveric kidneys, and require post-transplantation dialysis. The longer a DGF patient requires dialysis following transplantation, the greater the risk of diminished renal function and graft viability. There is currently no marketed drug therapy for the prevention or treatment of DGF.

BB3 is a proprietary small molecule with hepatocyte growth factor (HGF)-like therapeutic activities discovered and developed by Angion. Consistent with its HGF-like activities, BB3 has demonstrated organ protective and regenerative therapeutic effects in preclinical models of kidney and other major organ diseases. BB3 has been granted Orphan Drug and Fast Track designations by the FDA for renal transplantation. Angion retains worldwide rights to BB3.

Summary of Phase 2 Results

Recently, an interim analysis of a double-blind, placebo-controlled, multicenter Phase 2 trial revealed that BB3 administered 24 hours after renal transplantation met the primary and secondary endpoints of the trial protocol. BB3 improved urine output, lowered serum creatinine levels, reduced the duration of dialysis, and shortened hospital stay. The drug was well-tolerated and no treatment-related serious adverse events (SAEs) were reported. Angion is submitting these data for presentation at the American Society of Nephrology 2015 annual meeting.

“We are highly encouraged by the Phase 2 clinical data that support the initiation of our pivotal Phase 3 trial,” said Itzhak D. Goldberg M.D., FACR, President and CEO of Angion. “These data correlate very well with our preclinical studies and support our hypothesis that BB3 should reduce the severity of DGF even when administered 24 hours after transplantation. We are excited to begin enrollment of the Phase 3 study.”

“The waiting list for kidney transplants is long, and many waitlisted patients die on dialysis. We are reluctant to use many marginal kidneys for our patients because of the increased risk of delayed graft function and reduced long term graft survival. The availability of a drug that improves the function and longevity of transplanted marginal kidneys can have a transformative impact on the field and greatly shorten the waitlist for transplant

candidates," said Hamid Rabb, M.D., Professor of Medicine and Medical Director of the Kidney Transplant Program, The Johns Hopkins University. "Confirming Angion's Phase 2 data in Phase 3 would represent a major breakthrough in renal transplantation and could benefit countless patients."

In addition to Angion's Phase 3 DGF clinical trial, Angion has also filed an investigational new drug application with the FDA in order to conduct a multicenter Phase 2 trial of BB3 to prevent acute kidney injury (AKI) following cardiac surgery. Enrollment in this Phase 2 AKI trial is projected to start in the second half of 2015.

About Angion Biomedica Corp.

Angion Biomedica Corp. is a biopharmaceutical company established in 1998 to discover and develop novel therapeutic agents to treat acute and chronic organ dysfunction by harnessing the body's protective, reparative and regenerative systems. Our programs are currently focused on renal transplantation, acute kidney injury and chronic kidney disease. For further information, please visit www.angion.com, or contact us at mail@angion.com.

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