



Vasomune and AnGes Announce Drug Candidate AV-001 Receives Positive Recommendation of moving to the Cohort with highest dose from the IDSMB for AV001-004 Phase 2a Study

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TORONTO - (BUSINESS WIRE) - Vasomune Therapeutics Inc., a clinical-stage biopharmaceutical company focused on the development of AV-001 for the treatment of diseases associated with vascular dysfunction, announced today that their lead drug candidate AV-001 has received a positive recommendation of moving to the Cohort with highest dose from the Independent Data and Safety Monitoring Board (IDSMB) of the AV001-004 Phase 2a Study, NCT05123755.

"We are pleased to announce that the IDSMB recommended the continuation of the Phase 2a study evaluating the safety, tolerability and efficacy of AV-001 in patients hospitalized with pneumonia," said Shahid Ahmad, Vice-President of Operations and Planning. "We believe outcomes for patients experiencing or at risk of acute respiratory distress syndrome, of which pneumonia remains the most prevalent risk factor, can be improved through restoration of Tie2 signaling which promotes endothelial stability, enhances barrier defense and blocks vascular leak. Continuation of the Phase 2a study is a significant development milestone for AV-001 and is the result of strong collaborative efforts with our dedicated clinical investigators and advances Vasomune's FDA-designated Fast Track development objectives. Vasomune is indebted to the United States Department of Defense Congressionally Directed Medical Research Programs award #PR203503 for support of study AV001-004."

Ei Yamada, President & CEO of AnGes, said that "We are encouraged by the IDSMB decision to continue AV001-004 to the final Cohort. Our commitment to completing this important clinical study will allow us to take a step forward in the treatment of ARDS, for which there is no established standard of care."

About AV-001

Originally discovered and designed at Sunnybrook Research Institute at Sunnybrook Hospital in Toronto, AV-001 is being developed by Vasomune Therapeutics, Inc. under a co-development agreement with AnGes, Inc. [TYO: 4563]. AV-001 is a novel investigational medicine that targets the Tie2 receptor, a transmembrane protein most highly expressed on the surface of endothelial cells in the vasculature. AV-001 activates the nonredundant Tie2-Angiopoietin signaling axis, and through stimulation of multiple downstream pathways normalizes the vasculature by enhancing endothelial cell stability, restoring normal barrier defense, and blocking vascular leak. Vascular dysfunction contributes to the underlying disease pathophysiology in patients with bacterial and viral acute respiratory distress syndrome, sepsis, hemorrhagic shock, acute kidney injury, stroke, and vascular dementia. Importantly, in multiple pre-clinical studies AV-001 tightened endothelial cell-cell junctions and promoted endothelial cell survival, which reduced pulmonary edema, and improved lung function compared to untreated controls translating into significantly improved survival.

About Vasomune Therapeutics, Inc.

Vasomune Therapeutics, Inc. is a private clinical-stage biopharmaceutical company developing the next generation of medicines to harness the body's ability to defend against illness. Founded in 2014, Vasomune has focused on vascular normalization strategies, and has progressed the lead candidate AV-





001 from bench to bedside. Vascular dysfunction is associated with the pathology of several disease states, including bacterial and viral acute respiratory distress syndrome, sepsis, hemorrhagic shock, acute kidney injury, stroke, and vascular dementia. Vasomune's corporate headquarters and laboratories are in Toronto, Canada with US offices in Raleigh, NC. For more information about the company please visit www.vasomune.com.

About AnGes, Inc.

AnGes, Inc., a biopharmaceutical company founded in December 1999, focuses on the development of gene-based medicines. Collategene_® (HGF-plasmid gen therapy) is the AnGes' first product in clinical development for CLTI (Chronic Limb-Threatening Ischemia) in the U.S. It was granted Breakthrough designation by FDA in 2024, which will accelerate its development. AnGes is currently working on the development of a Tie2 tyrosine kinase receptor agonist (AV-001) for viral and bacterial-associated pneumonia and an NF- κ B decoy oligonucleotide for chronic discogenic lumbar back pain. For more information, visit www.anges.co.jp/en/