Vasomune and AnGes Announce Drug Candidate AV-001 Receives Positive Recommendation from the IDSMB of the AV-001-004 Phase 2a Study

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TORONTO–(BUSINESS WIRE)–Vasomune Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on the development of novel therapeutics for the treatment of diseases associated with vascular dysfunction, announced today that the lead drug candidate AV-001 has received a positive recommendation from the IDSMB of the AV-001-004 Phase 2a Study .

“We are pleased to announce that the Independent Data Safety Monitoring Board (IDSMB) recommended the continuation of the Phase 2a trial (NCT05123755) evaluating the efficacy, safety, and tolerability of AV-001 in patients suffering with Acute Respiratory Distress Syndrome (ARDS)” said Dr. Brian E. Jahns, President and Chief Operating Officer. “We believe outcomes for patients with ARDS can be significantly improved through restoration of Tie2 signaling to promote endothelial stability, enhance barrier defense and block vascular leak. The phase 2a study, AV-001-004, signifies focus effort by our investigators and the Vasomune team, and the faith and support provided by two prestigious US Department of Defence grants.”
Ei Yamada, President & CEO of AnGes, said that “Data gained in this important clinical study will inform the treatment of ARDS, and the clinical development of AV-001 is expected to accelerate with this milestone.”

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 COVID-19, influenza, bacterial sepsis, acute kidney injury, glaucoma, hemorrhagic shock, sepsis, stroke, and complications associated with diabetes. 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 discovers and develops drugs using a novel therapeutic approach

focused on vascular normalization strategies. Vascular dysfunction is associated with the pathology of several disease states, including COVID-19, viral and bacterial-associated pneumonia, acute kidney injury, glaucoma, hemorrhagic shock, sepsis, stroke, and complications associated with diabetes. Vasomune's corporate headquarters and laboratories are located 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. In March 2019, AnGes obtained conditional and time-limited approval for its lead product, Collategene® (Hepatocyte Growth Factor; HGF—plasmid gene therapy), for the treatment of lower limb ischemic ulcers. In September 2019, AnGes commenced commercialization in Japan of Collategene®, the world's first marketed drug using plasmid DNA. AnGes is currently working on the development of a Tie2 tyrosine kinase receptor agonist (AV-001) for COVID-19, viral and bacterial-associated pneumonia and an NF-κB decoy oligonucleotide for chronic discogenic lumbar back pain. Furthermore, AnGes acquired EmendoBio in December 2020 to expand its capabilities in genome-editing technologies. For more information, visit https://www.anges.co.jp/en/.