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Company Name: AnGes Inc.
Presentative: Ei Yamada, President & CEO

FDA Allowance of IND Application For AV-001 for the Treatment of Hospitalized Patients with COVID-19

November 13, 2020 – AnGes, Inc. and Vasomune Therapeutics, Inc., a clinical-stage biopharmaceutical company, announced the U.S. Food and Drug Administration (FDA) has allowed its Investigational New Drug (IND) application for AV-001, a Tie2 tyrosine kinase receptor agonist, as a potential treatment for hospitalized patients diagnosed with moderate-to-severe COVID-19 disease.

“FDA allowance of the IND application represents a significant milestone for Vasomune and marks the transition of the company to clinical development of a novel investigational medicine targeting the vascular response to SARS-CoV-2 infection for the treatment of seriously ill patients with COVID-19,” said Douglas Hamilton, President and CEO of Vasomune. “We are excited about potential benefit this first-in-class therapy might have for patients in the fight against the COVID-19.”

Originally discovered and designed at Sunnybrook Hospital in Toronto, AV-001 is being developed by Vasomune Therapeutics, Inc. under a co-development agreement with AnGes, Inc.

“There is an urgent need for therapeutics to treat patients with moderate-to-severe COVID-19 that require oxygen support”, said Ei Yamada, President and CEO of AnGes, Inc., “and we are encouraged by the preclinical findings that indicate this therapeutic approach might be particularly well-suited for hospitalized patients with COVID-19.”

About AV-001
AV-001 is a novel investigational medicine that targets the Tie2 receptor, a transmembrane protein target most highly expressed on the surface of endothelial cells in the vasculature. AV-001 activates the Tie2-Angiopoietin pathway and restores normal vascular function and endothelial stability. Vascular dysfunction contributes to the underlying disease pathophysiology in patients with COVID-19 and acute respiratory distress syndrome (ARDS), especially in patients with preexisting vascular comorbidities, such as hypertension, diabetes and obesity. Emerging evidence suggests SARS-CoV-2 infects pulmonary endothelial cells and causes microvascular leaks, contributing to the initiation and propagation of respiratory distress and ARDS in COVID-19 patients by altering blood vessel barrier integrity, promoting a coagulated state, inducing vascular inflammation (endotheliitis) and mediating inflammatory cell migration. In preclinical studies involving a lethal RNA virus infection animal model of influenza/ARDS, AV-001 has been shown to stabilize the vasculature by enhancing endothelial cell stability, restoring normal barrier defense and blocking vascular leak. Importantly, AV-001 monotherapy significantly improved survival and lung function compared to untreated controls and showed the benefit of enhanced recovery in combination with antiviral therapy. AV-001 is being developed for the treatment of moderate to-severe COVID-19 and ARDS.

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. Originally founded in 2006, 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, influenza-associated ARDS, acute lung injury, acute kidney injury, hemorrhagic shock, sepsis and stroke. Vasomune's corporate headquarters and laboratory is located in Toronto, Canada with US offices in San Mateo, CA. For more information about the company and its product candidates, please visit www.vasomune.com

About AnGes, Inc.
AnGes, Inc. is a biopharmaceutical company founded in December 1999 based on innovative discoveries by researchers at Osaka University and focuses on the development of gene-based medicines. Regarding AnGes, Inc.'s lead product, Collategene® (HGF plasmid gene therapy) for the treatment of critical limb ischemia, the company obtained conditional and time-limited approval in March 2019 and its commercialization started in September 2019 in Japan. Collategene® is the world's first marketed drug using plasmid DNA. Development of NF-κB decoy oligonucleotide for diseases, including lower back pain, and DNA vaccines for hypertension is also underway. Furthermore, AnGes, Inc. began co-development of a DNA vaccine for COVID-19 in Japan with Osaka University starting in March 2020. The DNA vaccine for COVID-19 utilizes proprietary plasmid DNA technology. For more information, visit https://www.anges.co.jp/en/

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