Affinia Therapeutics Announces Indications for Lead Gene Therapy Programs to Advance the Treatment of Neurologic and Neuro-oncologic Diseases supported by Multi-Year Manufacturing Agreement with Lonza Group

– *Indications include metachromatic leukodystrophy, a rare, progressive, and fatal disease affecting the nervous system, and brain metastases secondary to HER2+ breast cancer, a common and deadly form of cancer* –

– *Affinia Therapeutics to use its proprietary technologies and capsids with improved properties to bring the promise of gene therapy to patients with rare and prevalent devastating diseases* –

– *To support clinical supply, Affinia Therapeutics has entered into a multi-year strategic manufacturing agreement with Lonza Group, a founding investor* –

WALTHAM, Mass. – September 8, 2021 – Affinia Therapeutics, an innovative gene therapy company with a proprietary platform for rationally-designed adeno-associated virus (AAV) capsids developing gene therapies for rare and prevalent devastating diseases, today announced the first two indications it will pursue with its next-generation gene therapies: metachromatic leukodystrophy (MLD), a rare, progressive, and fatal neurodegenerative disease, and brain metastases secondary to human epidermal growth factor receptor 2 positive (HER2+) breast cancer (BMBC), a common and deadly form of cancer. The company's therapeutic candidates for these two indications are directed at targets in the central nervous system (CNS) and are based on its proprietary capsid, Anc80L65, which when delivered intrathecally has been observed to be 40-times more efficient at delivering genetic payloads to regions of the brain than AAV9, a capsid used by others in the field for CNS-directed gene therapies.

"Our goal in designing new capsids and promoters, as well as our focus on improved manufacturing approaches, is to address the current limitations of AAV gene therapies and build an expansive portfolio of potential first-in-class and best-in-class gene therapies to treat both rare and prevalent diseases," said Charlie Albright, Ph.D., chief scientific officer of Affinia Therapeutics. "Our initial two indications illustrate the range we believe our platform has to address both a devastating rare pediatric monogenic disease and a devastating complication of breast cancer. We look forward to advancing these programs into the clinic."

MLD is a rare progressive genetic disease that results from the deficiency of functional arylsulfatase A (ARSA), an enzyme that is critical for neuronal cell survival. Patients with the most common form of MLD, called late infantile MLD, typically die before the age of eight years. Affinia Therapeutics' product candidate Anc80L65-ARSA is designed to deliver a functional ARSA transgene via a one-time dose to the CNS through a routine outpatient lumbar puncture (LP) administration. By leveraging its proprietary Anc80L65 capsid that has shown rapid and broad gene expression in the CNS in preclinical models, the company hopes to achieve rapid and broad expression of the ARSA enzyme in the CNS and peripheral nervous system, resulting in transformative clinical benefit.

BMBC is a common and deadly complication of HER2+ breast cancer with a median survival of only 18 months. Trastuzumab is an approved monoclonal antibody for the treatment of HER2+ breast cancer, however current methods of administration are impractical for achieving sustained therapeutic levels in the brain sufficient to be effective against BMBC. Affinia Therapeutics' product candidate Anc80L65-trastuzumab is designed to be given as a one-time dose by LP administration to deliver the genetic code that enables the cells in the brain to produce their own trastuzumab in close proximity to the brain

metastases. The company's pharmacokinetic modeling analysis showed that the levels of trastuzumab in the brain achieved by its gene therapy approach are up to 100 times higher than those achieved by current methods of administration. The company believes that its approach results in trastuzumab levels in the brain higher than those needed to be effective for BMBC and will result in transformative clinical benefit.

Strategic Manufacturing Agreement with Lonza Group
To support supply for its initial clinical programs, Affinia Therapeutics has entered into a multi-year, non-exclusive agreement with Lonza Group in which Lonza will provide contract development and manufacturing services to Affinia Therapeutics for its initial product candidates. Lonza has significant experience with novel capsids, and supported the development of Affinia Therapeutics' foundational technology in the lab of Dr. Luk Vandenberghe, Ph.D. at Massachusetts Eye and Ear. More recently, Lonza has worked with Affinia Therapeutics to achieve a four-fold improvement in yield for the company's lead capsid, Anc80L65. Lonza and Affinia Therapeutics are partnering with the goal of ensuring flexible manufacturing capacity for the next several years.

Alberto Santagostino, SVP, Head of Cell and Gene Technologies at Lonza, commented: "Affinia Therapeutics is leading the way in the AAV gene therapy space, introducing innovative solutions and platforms to treat life-threatening diseases. Supporting the development and manufacture of Affinia Therapeutics' initial product candidates reflects the evolution of our relationship with the company. We are pleased to take on the role of developing and manufacturing the production of these novel therapies, leveraging our experienced teams and commercially approved facilities to de-risk and scale-up their manufacturing processes, with the end-goal of making them accessible for patients in need."

About Affinia Therapeutics
Affinia Therapeutics is pioneering a shift to a new class of rationally-designed gene therapies that treat rare and prevalent diseases. Affinia Therapeutics' proprietary Affinia Rationally-designed Therapeutics (ART) platform consists of three pillars intended to synergistically improve the efficacy, safety, and manufacturability of AAV-based gene therapies though the development of next-generation capsids, promoters, and manufacturing approaches. Affinia Therapeutics' current pipeline consists of five programs in the neurology, neuro-oncology, muscle, and lung therapeutic areas, and spans gene replacement, vectorized antibody, and gene editing modalities. For more information, visit https://www.affiniatx.com.

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