Agilis Biotherapeutics and Gene Therapy Research Institution

Enter into Strategic Partnership

Companies form Joint Venture to Advance Gene Therapy Manufacturing and Clinical Programs

Cambridge, MA, and Tokyo – August 2, 2017 -- Agilis Biotherapeutics, Inc. (Agilis), a biotechnology company advancing innovative DNA therapeutics for rare genetic diseases that affect the central nervous system (CNS), and Gene Therapy Research Institution Co, Ltd. (GTRI), a corporation with the mission of developing and delivering of the safest and most efficient gene therapies, today announced that the companies have completed a manufacturing and collaboration partnership joint venture (JV) to advance adeno-associated virus (AAV) gene therapies. The JV was initiated earlier this year in connection with a grant from the Japanese Ministry of Trade, Economics and Industry (METI) and Japan External Trade Organization (JETRO) for the development of a state-of-the-art AAV manufacturing facility in Japan. GTRI was co-founded by Professor Shin-ichi Muramatsu, M.D., a leading pioneer in gene therapy who has performed basic science and clinical research in the field for over two decades.

The JV, headquartered in Japan, will initially focus on developing and manufacturing AAV gene therapy vectors using Sf9 baculovirus and HEK293 mammalian cell systems and operate a process development and production facility located in the Tokyo area designed to meet international manufacturing standards, including cGMP, GCTP and PIC/S GMP requirements. Agilis and GTRI will also collaborate to expedite the development, approval and commercialization of select gene therapies in specific CNS diseases. Terms of the joint venture were not disclosed.

"We are pleased to collaborate with Agilis to leverage each organization's capabilities and know-how, advance the manufacturing state-of-the art for gene therapy, and develop novel gene therapies," commented Katsuhito Asai, Chief Executive Officer of GTRI and a Director of the joint venture. "Our partnership will seek to capitalize on the strong recent progress in the field of gene therapy and expedite the development of innovative gene therapies for patients in need, with a major emphasis on the quality production of safe, effective therapeutics."

"We are thrilled to partner with GTRI," said Mark Pykett, Agilis CEO and a Director of the joint venture. "We believe that our partnership will enhance the efforts of both organizations, build important shared production capabilities, and accelerate development and commercialization of important gene therapies. We look forward to working with GTRI on a range of initiatives."

Agilis Biotherapeutics

Agilis is advancing innovative gene therapies designed to provide long-term efficacy for patients with debilitating, often fatal, rare genetic diseases that affect the central nervous system. Agilis' gene therapies are engineered to impart sustainable clinical benefits by inducing persistent expression of a therapeutic gene through precise targeting and restoration of lost gene function to achieve long-term efficacy. Agilis' rare disease programs are focused on gene therapy for AADC deficiency, Friedreich's ataxia, and Angelman syndrome, all rare genetic diseases that include neurological deficits and result in physically debilitating conditions.

We invite you to visit our website at www.agilisbio.com

About GTRI

GTRI, a bio-tech venture in Japan, was founded in May 2014 based on the pioneering research of Dr. Shin-ichi Muramatsu, focusing on gene therapy using AAV vector as the leading company in Japan in this field. Its pipeline includes more than 20 diseases, targeting CNS diseases and

monogenic disorders, such as Parkinson's disease, AADC deficiency, ALS, Alzheimer's disease, spinocerebellar degeneration, Tay-Sachs disease, GLUT1 deficiency, and others.

Dr. Muramatsu, PhD, MD, of Jichi Medical University, is one of the top researchers of AAV vectors and AAV-mediated gene therapy in the world. He originated AAV3 in 1995 during his research at the NIH, USA, and afterwards developed his original modified AAV3/9 in Japan, which enables to deliver the gene of interest effectively in CNS through the blood-brain barrier.

Safe Harbor Statement

Some of the statements made in this press release are forward-looking statements. These forward-looking statements are based upon our current expectations and projections about future events and generally relate to our plans, objectives and expectations for the development of our business. Although management believes that the plans and objectives reflected in or suggested by these forward-looking statements are reasonable, all forward-looking statements involve risks and uncertainties and actual future results may be materially different from the plans, objectives and expectations expressed in this press release.

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