Atamyo Therapeutics Reaches Significant Regulatory and Financial Milestones for ATA-100, its Gene Therapy to Treat Limb-Girdle Muscular Dystrophy Type 2I/R9

- *Additional approval of Clinical Trial Application received from Denmark Danish Medicines Agency (DKMA)*
- *Orphan Drug Designation awarded from US FDA and European EMA*
- *Non-dilutive public financing of 2 million euros received from Bpifrance*

Evry, France (February 24, 2022) - Atamyo Therapeutics, a biotechnology company focused on the development of new-generation gene therapies targeting neuromuscular diseases, today announced multiple major regulatory and financial milestones for ATA-100, a one-time gene therapy for the treatment of fukutin-related protein (FKRP) limb-girdle muscular dystrophy Type 2I/R9 (LGMD2I/R9).

A second authorization of a Clinical Trial Application (CTA) in Europe was granted by the Denmark Medicines Agency (DKMA) for ATA-100. A first CTA approval had been granted by the United Kingdom Medicines & Healthcare products Regulatory Agency (MHRA) and an additional CTA is currently under review in France.

ATA-100 has also been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) for the treatment of LGMD-R9, and by the European Medicines Agency (EMA) for the treatment of LGMD. Orphan Drug Designations by the FDA and the EMA grant seven and ten years of market exclusivity in the US and Europe, respectively, and provide with other benefits such as tax credits, protocol assistance and research grants.

Atamyo was also awarded a non-dilutive public financing of 2 million euros by Bpifrance to support the initiation of the first-in-man clinical trial of ATA-100. This financing is part of the Deeptech Development Aid program, a financing initiative from the French government to support new and emerging industries within France.

“We are thrilled by this additional approval for our first-in-human trial with ATA-100 and by the Orphan Drug Designation in the United States and in Europe. This single-administration treatment brings hope to patients with LGMD2I/R9”, said Stéphane Degove, CEO of Atamyo Therapeutics. “The strong financial support by the French government will reinforce the rapid progress towards a first administration of ATA-100 in patients.”

LGMD2I/R9 is a rare genetic disease caused by mutations in the gene that produces fukutin-related protein (FKRP). It affects an estimated 5,000 people in the US and Europe. Symptoms appear around late childhood or early adulthood. Patients suffer from progressive muscular weakness leading to loss of ambulation. They also are prone to respiratory impairment and myocardial dysfunction. There are currently no curative treatments for LGMD2I/R9.

ATA-100, a single-administration gene therapy candidate for LGMD2I/R9, delivers a normal copy of the gene for production of FKRP proteins. The therapy is based on the research of

Atamyo Chief Scientific Officer Isabelle Richard, Ph.D., Research Director at CNRS who heads the Progressive Muscular Dystrophies Laboratory at Genethon.

About Atamyo Therapeutics
Atamyo Therapeutics is focused on the development of a new generation of effective and safe gene therapies for neuromuscular diseases. A spin-off of gene therapy pioneer Genethon, Atamyo leverages unique expertise in AAV-based gene therapy and muscular dystrophies from the Progressive Muscular Dystrophies Laboratory at Genethon. Atamyo's most advanced programs address different forms of limb-girdle muscular dystrophies (LGMD). The name of the company is derived from two words: Celtic Atao which means "Always" or "Forever" and Myo which is the Greek root for muscle. Atamyo conveys the spirit of its commitment to improve the life of patients affected by neuromuscular diseases with life-long efficient treatments. For more information visit www.atamyo.com

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