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ReiThera Manufactures Vectors for EG 427's Phase 1b/2a Gene Therapy Clinical Trial for Neurological Bladder Disorder

- **ReiThera began supplying GMP-grade material for EG 427's Phase 1b/2a trial of EG110A, a gene therapy for patients with neurogenic detrusor overactivity (NDO).**
- **EG110A targets bladder neurons to control overactivity while preserving function.**
- **NDO affects 70-84% of spinal cord injury patients, causing serious health issues.**

Rome, Italy, October 21, 2024 - **ReiThera**, the GMP viral manufacturer for novel therapies, released the first lot of a non-replicative HSV-1 vector that will support EG 427's Phase 1b/2a clinical trial of EG110A, an *in vivo* gene therapy targeting neurogenic detrusor overactivity (NDO) in patients with spinal cord injury (SCI). EG 427, a French biotech leading the development of pinpoint DNA medicines for prevalent diseases in neurology, chose ReiThera due to its long-term expertise in manufacturing high-quality viral vectors compliant with regulatory requirements. EG 427 recently announced it has received Investigational New Drug (IND) clearance from the U.S. Food and Drug Administration (FDA) for the EG110A-based gene therapy. The phase 1b/2a clinical study is to take place in four leading U.S. institutions.

NDO is a common but difficult-to-treat complication of neural damage from SCI as well as diseases like multiple sclerosis. NDO causes uncontrolled urinary incontinence, risk of kidney damage as well as urinary tract infections than can lead to death in 5-10% of the SCI population. It also represents a major burden leading to strong impact on patient's quality of life. EG110A is designed to selectively silence the signals of key bladder sensory neurons responsible for bladder muscle overactivity while preserving motor neurons and retaining normal bladder function.

EG110A was produced at ReiThera manufacturing plant in Rome. ReiThera worked with EG 427 to develop processes to enhance vector yield in a fixed-bed bioreactor. In addition, the GMP manufacturing was set up to meet the sterility compliance typical of non filtrable vectors and Media Process Simulation - Media filling simulation have been performed before Drug Substance & Drug product production. The role of ReiThera in supplying the GMP material was crucial to advancing this innovative therapy into clinical development.

"As a company dedicated to advancing innovative therapies, we are proud to have provided the GMP-grade material necessary for the successful initiation of EG 427's Phase 1b/2a clinical trial. Our partnership in supporting the development of EG110A, a promising gene therapy for NDO in spinal cord injury patients, highlights ReiThera's commitment to delivering high-quality solutions for cutting-edge medical advancements. We believe this collaboration marks an important step in improving the lives of patients affected by challenging neurological conditions," said Stefano Colloca, Chief Executive Officer at Reithera.

"We found in ReiThera a great partner with the scientific expertise, with the flexibility necessary to develop and optimize our GMP manufacturing process and provide us with the quality product necessary for our early stage clinical development," said Philippe Chambon, Chief Executive Officer at EG 427.

About Reithera
ReiThera Srl is a CDMO company dedicated to technology, process development and GMP manufacturing, providing support for the clinical translation of genetic vaccines and medicinal products for advanced therapies. The company has extensive expertise in developing scalable processes for viral vector manufacturing and a consolidated experience in GMP production of adeno-associated vector (AAV), lentivirus, adenoviral vector (AdV), modified vaccinia Ankara and herpes simplex vector.
ReiThera's core manufacturing capacity is based in a state-of-the-art facility, which includes stirred-tank bioreactors at scales of 50L, 200L, 1000L, and 2000L, as well as fixed-bed bioreactors for cell growth in adherence. The GMP facility also comprises an automatic filling suite and quality control laboratories. ReiThera's headquarters, R&D laboratories, and GMP facilities are located in Rome, Italy. For more information, visit www.reithera.com

About EG 427
EG 427 is the second company to bring a non-replicating HSV-1 (nrHSV-1) vector into clinical development, with an Investigational New Drug (IND) cleared by the U.S. Food and Drug Administration (FDA) in June 2024. It will be the first human trial of such a vector, targeting sensory neuron-based diseases. The product, EG110A, addresses multiple severe bladder diseases, such as neurogenic bladder (NDO) and overactive bladder (OAB), and has the potential to be a major improvement over existing therapies, resulting in better care for patients and lower costs for healthcare systems.
The company's unique platform delivers pinpoint neurotherapeutics to treat prevalent diseases of the peripheral and central nervous system. Its vectors can achieve focal transduction in specific regions and then selective expression of transgenes in targeted subsets of neurons thanks to the control of sophisticated regulatory elements. With demonstrated clinical safety and possible repeated dosing, the large payload capacity of nrHSV-1 vectors allows either for long-term gene therapy, or all-in-one gene editing approaches.