EG 427

PINPOINT GENE THERAPY

Press Release

EG 427 Receives U.S. FDA Fast Track Designation for EG110A DNA Medicine in Neurogenic Bladder Patients

- Builds on positive top-line data from first cohort demonstrating significant reduction in urinary incontinence episodes

Paris, France, October 6, 2025 – EG 427, a biotechnology company leading the development of pinpoint DNA medicines for prevalent chronic diseases in neurology, announced today that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to EG110A, its novel DNA therapy for the treatment of neurogenic detrusor overactivity (NDO). EG110A is a non-replicative HSV-1 vector designed to selectively silence the signals from type C sensory neurons responsible for the bladder muscle overactivity, whilst preserving other bladder controls. NDO is a common urinary bladder dysfunction caused by spinal cord injury (SCI) and other neurodegenerative diseases, such as multiple sclerosis or Parkinson's disease.

"The FDA's decision to grant Fast Track designation to EG110A demonstrates the urgent need for more effective therapies for individuals living with neurogenic detrusor overactivity," said Philippe Chambon, MD, PhD, Chief Executive Officer at EG 427. "We welcome the opportunity to work more closely with the FDA as we advance EG110A through clinical development, building on the very promising clinical results we announced last week. Top-line data showed for the first time in a chronic neuro-urological condition that treatment with our DNA medicine EG110A reduced incontinence episodes by over 88% by the predetermined 12 week timepoint."

Treatment of NDO in people with SCI with the lowest dose of EG110A was found to reduce the incidence of urinary incontinence episodes by over 88% by week 12, with effect already clearly established at week 4. EG110A also demonstrated a good safety profile in all patients treated to date.

The U.S. FDA Fast Track program is designed to facilitate the development and expedite the review of investigational drugs with potential to address unmet medical needs in serious or life-threatening conditions. Product candidates with Fast Track designation are eligible for priority review and accelerated approval, if relevant criteria are met.

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. NDO affects most (70-84%) patients living with SCI, an estimated total of 300,000-400,000 worldwide. Altogether, NDO affects at least 2 million patients suffering from SCI, multiple sclerosis, Parkinson's and other neurodegenerative diseases, across the seven major markets and has a significant impact on their quality of life. The European Association of Urology recently estimated that incontinence caused by NDO and other indications, such as

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overactive bladder, represents a growing economic burden of over €69.1 billion in 2023 in Europe[1].

About EG 427

EG 427 is the global leader in non-replicating HSV-1 (nrHSV-1) vector technology in neurology. EG 427 has started a phase 1/2 study in the US with its lead DNA medicine candidate, EG110A, in patients with neurogenic detrusor overactivity (neurogenic bladder)-related incontinence. This is the first human study of this type of a vector targeting sensory neuron-based diseases. EG110A is being developed to addresses multiple severe bladder diseases, including 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 HERMES 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 for versatile DNA delivery for smarter DNA medicine.

For more information:
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