

## Cyllene Therapeutics Receives U.S. FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for EG110A in Neurogenic Detrusor Overactivity (NDO)

- RMAT designation follows proof of concept demonstration of strong, lasting efficacy and good safety profile in initial NDO Phase 1b/2a trial ongoing in the US.
- EG110A is the first non-systemic, site-specific inhibitor of CGRP+ neurons, with initial applications to treat severe bladder disorders. A single treatment course could potentially provide long-lasting symptomatic relief in patients.

**Paris, France and New York, USA, September 14, 2026** - Cyllene Therapeutics ("Cyllene Tx"), the global leader in non-systemic, site-specific therapies for neurological disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation to its lead candidate, EG110A, a first-in-class treatment being developed to address neurogenic detrusor overactivity (NDO) with urinary incontinence. EG110A is a non-replicating HSV-1 vector designed to selectively silence CGRP+ (type C) sensory neurons responsible for bladder muscle overactivity, whilst preserving normal bladder function. The first of a pipeline of products developed from Cyllene Tx's proprietary HERMES platform, EG110A's properties reflect the inherent safety and redosability characteristics possessed by non-replicative herpes vectors.

RMAT designation was granted based on initial positive results from an ongoing study of EG110A in patients with neurogenic detrusor overactivity associated with spinal cord injury (SCI). Interim results will be presented at the International Continence Society (ICS) annual conference on October 7, 2026, in Maastricht.

"Receiving RMAT designation from the FDA for EG110A is a key milestone in the history of the company. It recognizes the critical need to provide better therapeutic solutions to patients affected by severe urinary incontinence as well as the encouraging initial clinical results we have achieved to date," said Philippe Chambon, MD, PhD, Co-Founder and Chief Executive Officer of Cyllene Tx.

"The clinical data seen to date, demonstrating a marked reduction in urinary episodes, suggests treatment with EG110A could have a profound impact on the daily lives of patients. We look forward to working closely with the FDA as we move further into clinical development, including a planned Phase 2b/3 study with EG110A in neurogenic detrusor overactivity in 2027," said Cornelia Haag-Molkenteller, MD and Chief Medical Officer at Cyllene Tx.

The FDA's RMAT designation is designed to expedite development and review of regenerative medicine therapies, including genetic medicines, to treat, modify, reverse or

cure serious diseases or conditions. To be eligible, preliminary clinical evidence must indicate that the regenerative medicine therapy has the potential to address those unmet medical needs. The RMAT designation builds on the Fast Track designation for EG110A granted in October 2025. It provides further opportunity to interact more closely and frequently with the FDA, and receive guidance on innovative trial design, surrogate or intermediate endpoints to support potential accelerated approval, as well as new approaches to address post-approval requirements.

### **About Neurogenic Detrusor Overactivity (NDO)**

NDO is a bladder dysfunction caused by neurological injury or disease, which 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 with urinary incontinence is a serious, chronic, and frequently permanent condition, highly prevalent in people living with SCI, multiple sclerosis or Parkinson's disease. Altogether, NDO affects at least 2 million patients 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 overactive bladder, represents a growing economic burden of over €69.1 billion in 2023 in Europe.

### **About Cyllene Therapeutics**

Cyllene Therapeutics is the global leader in non-systemic, site-specific therapies for neurological disorders. Cyllene Tx is currently executing a Phase 1b/2a 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 with nrHSV vectors targeting sensory neuron-based diseases. EG110A is a first-in-class DNA medicine being developed to address 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 and then selective expression of transgenes in targeted subsets of neurons. With demonstrated clinical safety and possible repeat dosing, the large payload capacity of nrHSV-1 vectors allows for versatile DNA delivery and smarter DNA medicine.

**For more information**  [www.cyllene-tx.com](http://www.cyllene-tx.com)

 [www.linkedin.com/company/cyllene-tx](https://www.linkedin.com/company/cyllene-tx)

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