# Entrada Therapeutics Receives Authorization in the European Union to Initiate ELEVATE-45-201, a Phase 1/2 Multiple Ascending Dose Clinical Study of ENTR-601-45 in Patients Living with Duchenne Muscular Dystrophy Amenable to Exon 45 Skipping

May 28, 2025

*– Company on track to begin ELEVATE-45-201 in Q3 2025 –*

*– Follows recently received Medicines and Healthcare Products Regulatory Agency authorization in the United Kingdom for ELEVATE-45-201 –*

BOSTON, May 28, 2025 (GLOBE NEWSWIRE) -- Entrada Therapeutics, Inc. (Nasdaq: TRDA) today announced it has received authorization from the Health Authorities and Ethics Committees of multiple countries under the European Union Clinical Trial Regulation (EU-CTR) to initiate ELEVATE-45-201, a Phase 1/2 multiple ascending dose (MAD) clinical study of ENTR-601-45 in patients living with Duchenne muscular dystrophy (DMD) who are amenable to exon 45 skipping.

"ELEVATE-45-201 is the most advanced clinical study of a conjugated exon skipping therapy for individuals amenable to exon 45 skipping and offers the potential to address a large Duchenne subpopulation with significant unmet medical needs," said Dipal Doshi, Chief Executive Officer at Entrada Therapeutics. "The EU authorization builds on the growing clinical momentum behind our novel Duchenne programs. With the recent authorizations of ELEVATE-44 and ELEVATE-45, and a planned filing for ELEVATE-50 later this year, we are on track to significantly expand the scope of our DMD franchise by year-end."

ELEVATE-45-201 is a global, two-part, randomized, double-blind placebo-controlled Phase 1/2 study evaluating the safety, tolerability and effectiveness of ENTR-601-45 in ambulatory patients with Duchenne who are exon 45 skipping amenable. Part A is a multiple ascending dose study designed to evaluate the safety, pharmacokinetics and pharmacodynamics, including exon skipping and dystrophin production in approximately 24 patients. Dosing will be administered every six weeks, with the planned doses across three cohorts anticipated to range from 5 mg/kg up to 15 mg/kg. Part B of the study will further evaluate the optimal dose established in Part A for safety and efficacy, including functional outcomes and patient reported quality of life measures. Study participants may be eligible to enter an open label extension study (OLE), in which the safety, efficacy and tolerability of ENTR-601-45 will be evaluated over a longer period of time. The Company is on track to initiate ELEVATE-45-201 in Q3 2025.

**About ENTR-601-45**
ENTR-601-45, a proprietary Endosomal Escape Vehicle (EEV™)-conjugated phosphorodiamidate morpholino oligomer (PMO), is the second product candidate within Entrada's Duchenne muscular dystrophy franchise from its growing pipeline of EEV-therapeutics. Each EEV-PMO therapeutic candidate has an oligonucleotide sequence designed and optimized for the specific subpopulation of interest. ENTR-601-45 is designed to address the underlying cause of Duchenne due to mutated or missing exons in the *DMD* gene. ENTR-601-45, an investigational therapy for the potential treatment of people living with Duchenne who are exon 45 skipping amenable, is being evaluated for its potential to restore the mRNA reading frame and allow for the translation of dystrophin protein that is slightly shortened but still functional.

**About Duchenne Muscular Dystrophy (DMD)**
Duchenne muscular dystrophy (DMD) is a rare disease caused by mutations in the *DMD* gene, which encodes for the dystrophin protein. These mutations lead to inadequate dystrophin production. Dystrophin is essential to maintaining the structural integrity and function of muscle cells. Lack of functional dystrophin leads to progressive loss of muscle strength, impacting mobility and causing heart or respiratory complications that contribute to high mortality rates. An estimated 41,000 people in the U.S. and Europe are living with Duchenne, and approximately nine percent of that population are exon 45 skipping amenable.

**About Entrada Therapeutics**
Entrada Therapeutics is a clinical-stage biopharmaceutical company aiming to transform the lives of patients by establishing a new class of medicines that engage intracellular targets that have long been considered inaccessible. The Company's Endosomal Escape Vehicle (EEV™)-therapeutics are designed to enable the efficient intracellular delivery of a wide range of therapeutics into a variety of organs and tissues, resulting in an improved therapeutic index. Through this proprietary, versatile and modular approach, Entrada is advancing a robust development portfolio of RNA- and protein-based programs for the potential treatment of neuromuscular and ocular diseases, among others. The Company's lead oligonucleotide programs are in development for the potential treatment of people living with Duchenne who are exon 44, 45, 50 and 51 skipping amenable. Entrada has partnered to develop a clinical-stage program, VX-670, for myotonic dystrophy type 1.

For more information about Entrada, please visit our website, www.entradatx.com, and follow us on LinkedIn.

**Forward-Looking Statements**
This press release contains express and implied forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding Entrada's strategy, future operations, prospects and plans, objectives of management, the validation and differentiation of Entrada's approach and EEV platform and its ability to provide a potential treatment for patients, expectations regarding Entrada's planned 1/2 MAD clinical study of ENTR-601-44 in the U.K. and EU, including its initiation in the U.K. and EU in the second quarter of 2025, expectations regarding Entrada's planned 1/2 MAD clinical study of ENTR-601-45 in the U.K. and EU, including its initiation in the U.K. and EU in the third quarter of 2025, the ability to recruit for and complete the ELEVATE-44-102 study in the U.S., including its initiation in the U.S. in the first half of 2026, the ability to recruit for and complete global Phase 2 clinical studies for ENTR-601-44, ENTR-601-45 and ENTR-601-50, expectations regarding the timing of global regulatory filings for the planned Phase 2 clinical studies for ENTR-601-50 in the second half of 2025, the potential therapeutic benefits of Entrada's EEV product candidates and the ability to advance therapeutic

candidates in indications beyond neuromuscular disease, including the potential for ENTR-601-44 to be a transformative treatment option, the continued development and advancement of ENTR-601-44, ENTR-601-45, ENTR-601-50, and ENTR-601-51 for the treatment of DMD and the partnered product candidate VX-670 for the treatment of DM1, expectations regarding the progress and success of Entrada's collaboration with Vertex, the ability to continue to expand and develop additional therapeutic programs, including further exon skipping programs, and the sufficiency of its cash resources into the second half of 2027, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Entrada may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the identification and development of product candidates, including the conduct of research activities and the initiation and completion of preclinical studies and clinical studies; uncertainties as to the availability and timing of results from preclinical and clinical studies; the timing of and Entrada's ability to submit and obtain regulatory clearance and initiate clinical studies; whether results from preclinical studies or clinical studies will be predictive of the results of later preclinical studies and clinical studies; whether Entrada's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in Entrada's filings with the Securities and Exchange Commission (SEC), including the Company's most recent Form 10-K and in subsequent filings Entrada may make with the SEC. In addition, the forward-looking statements included in this press release represent Entrada's views as of the date of this press release. Entrada anticipates that subsequent events and developments will cause its views to change. However, while Entrada may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Entrada's views as of any date subsequent to the date of this press release.

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