



Entrada Therapeutics Receives Authorization in the United Kingdom to Initiate Phase 1 Clinical Trial of ENTR-601-44 for the Potential Treatment of Duchenne Muscular Dystrophy

August 1, 2023

– First participant is expected to be dosed in September 2023 with data anticipated in the second half of 2024 –

– Cash runway extended through the end of 2025 –

BOSTON, Aug. 01, 2023 (GLOBE NEWSWIRE) -- Entrada Therapeutics, Inc. (Nasdaq: TRDA), a biopharmaceutical company aiming to transform the lives of patients by establishing intracellular Endosomal Escape Vehicle (EEV™)-therapeutics as a new class of medicines, today announced that it has received authorization from the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) and Research Ethics Committee (REC) for its CTIMP (Clinical Trial of an Investigational Medicinal Product) for a Phase 1 clinical trial in healthy volunteers for ENTR-601-44. ENTR-601-44 is Entrada's lead product candidate within its Duchenne franchise and is being developed for the potential treatment of individuals with Duchenne who are exon 44 skipping amenable.

"We are looking forward to this important next step in advancing ENTR-601-44 for the potential treatment of people with exon 44 skipping amenable Duchenne muscular dystrophy, where there exists a profound unmet medical need," said Dipal Doshi, President and Chief Executive Officer of Entrada Therapeutics. "This milestone, coupled with the extension of our cash runway through the end of 2025, positions Entrada to advance our Duchenne franchise while broadening the potential of our intracellular therapeutics across serious diseases."

The Phase 1 trial's primary objective is to evaluate the safety of a single dose of ENTR-601-44 in healthy volunteers, with a target enrollment of approximately 40 participants. The trial will also evaluate tolerability, pharmacokinetics and target engagement as measured by exon skipping in the skeletal muscle. The first participant is expected to be dosed in September of this year with data anticipated in the second half of 2024.

About ENTR-601-44

ENTR-601-44, a proprietary Endosomal Escape Vehicle (EEV™)-conjugated phosphorodiamidate morpholino oligomer (PMO), is the lead product candidate within its Duchenne franchise from Entrada's growing pipeline of EEV-therapeutics. Each EEV-PMO therapeutic candidate has an oligonucleotide sequence designed and optimized for the specific subpopulation of interest. ENTR-601-44 is designed to address the underlying cause of Duchenne muscular dystrophy due to mutated or missing exons in the *DMD* gene. ENTR-601-44, an investigational therapy for the potential treatment of people living with Duchenne who are exon 44 skipping amenable, has the 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

Duchenne muscular dystrophy is a rare genetic disease that causes progressive muscle degeneration and weakness throughout the body. Duchenne is caused by mutations in the *DMD* gene, which leads to inadequate production of dystrophin, a protein essential to maintaining the structural integrity and function of muscle cells. Duchenne causes progressive loss of muscle function throughout the body, which limits mobility and causes heart and respiratory complications in the later stages of the disease. Currently approved therapies for Duchenne seek to improve dystrophin production, but to date, the clinical benefits of these products have not been confirmed.

About Entrada Therapeutics

Entrada Therapeutics is a biopharmaceutical company aiming to transform the lives of patients by establishing a new class of medicines, Endosomal Escape Vehicle (EEV™)-therapeutics, to engage intracellular targets that have long been considered inaccessible and undruggable. The Company's 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 its proprietary, highly versatile and modular EEV platform, Entrada is building a robust development portfolio of RNA-, antibody- and enzyme-based programs for the potential treatment of neuromuscular, immunological, ocular and metabolic diseases, among others. The Company's lead oligonucleotide programs include ENTR-601-44 and ENTR-601-45 for the potential treatment of people living with Duchenne who are exon 44 and 45 skipping amenable, respectively, as well as our partnered candidate ENTR-701 targeting myotonic dystrophy type 1 (DM1).

For more information about Entrada, please visit our website, www.entradatx.com, and follow us on [LinkedIn](#).

Forward-Looking Statements

This press release contains 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, ability to initiate and recruit for a healthy volunteer trial for ENTR-601-44 in the United Kingdom with first subject dosed in September 2023, expectations regarding the timing of data from its Phase 1 trial for ENTR-601-44 in the second half of 2024, expectations regarding the safety and therapeutic benefits of ENTR-601-44, the potential of its EEV product candidates and EEV platform, the continued development and advancement of ENTR-601-44 and ENTR-601-45 for the treatment of Duchenne, and the sufficiency of its cash resources through 2025, 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 trials; 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 for IND applications and initiate clinical trials; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; 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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