Entrada Therapeutics Announces Clinical Hold on IND Application for ENTR-601-44 in Duchenne Muscular Dystrophy

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BOSTON, Dec. 19, 2022 (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 the Company received a clinical hold notice from the U.S. Food and Drug Administration (FDA) regarding their Investigational New Drug Application (IND) for ENTR-601-44 for the potential treatment of Duchenne muscular dystrophy. The FDA indicated they will provide an official Clinical Hold letter to Entrada within 30 days. The Company plans to share additional updates pending further communications with the Agency.

“The clinical hold on our ENTR-601-44 program is disappointing and we will work to address the FDA’s concerns regarding the IND,” said Dipal Doshi, President and Chief Executive Officer of Entrada Therapeutics. “There are no approved Duchenne therapies for people with exon 44 skippable mutations and we are eager to resolve this hold and continue down the treatment development pathway.”

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 oligonucleotide-, antibody- and enzyme-based programs for the potential treatment of neuromuscular diseases, immunology, oncology and diseases of the central nervous system. The Company’s lead oligonucleotide programs include ENTR-601-44 targeting Duchenne muscular dystrophy (DMD) and ENTR-701 targeting myotonic dystrophy type 1 (DM1).

For more information about Entrada, please visit our website, www.entradatx.com, and follow us on Twitter and 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, expectations regarding the timing and outcome of the Company’s discussions with the FDA regarding the clinical hold on the IND for ENTR-601-44, the Company’s ability to address the FDA’s concerns regarding its IND for ENTR-601-44, the timing of the Company’s Phase 1 single ascending dose trial for ENTR-601-44 and initial clinical readout for such trial, the ability to enroll patients and achieve successful results in ENTR-601-44 clinical trials, expectations regarding the findings from preclinical data of the Company’s therapeutic candidates, expectations regarding the continued development, advancement and the potential therapeutic benefits of ENTR-601-44 for the treatment of Duchenne, the timing of Entrada’s planned regulatory filings regarding its development programs, and the potential therapeutic benefits of its EEV candidates, 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 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; uncertainties associated with the impact of the ongoing COVID-19 pandemic on Entrada’s business and operations; 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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