Dyne Therapeutics Announces FDA Clinical Hold on IND Application for DYNE-251 in Duchenne Muscular Dystrophy

January 18, 2022

WALTHAM, Mass., Jan. 18, 2022 (GLOBE NEWSWIRE) -- Dyne Therapeutics, Inc. (Nasdaq: DYN), a muscle disease company focused on advancing innovative life-transforming therapeutics for people living with genetically driven diseases, today announced that the U.S. Food and Drug Administration (FDA) has placed on clinical hold its Investigational New Drug (IND) application to initiate a clinical trial of DYNE-251 in patients with Duchenne muscular dystrophy (DMD) amenable to skipping exon 51. Dyne received a clinical hold letter from the FDA on Friday, January 14, 2022 requesting additional clinical and non-clinical information for DYNE-251. The Company expects to submit to the FDA its response with data from existing and ongoing studies in the second quarter of 2022, and if satisfactory to the FDA, to be dosing patients in a Phase 1/2 multiple ascending dose (MAD) clinical trial of DYNE-251 by mid-2022 in accordance with its current guidance. Dyne will work closely with the FDA to resolve the clinical hold as promptly as possible.

As previously announced, the Company expects to submit an IND for DYNE-101 in myotonic dystrophy type 1 (DM1) during the first quarter of 2022 and to be dosing patients in a planned MAD clinical trial by mid-2022.

About Dyne Therapeutics

Dyne Therapeutics is building a leading muscle disease company dedicated to advancing innovative life-transforming therapeutics for people living with genetically driven diseases. With its proprietary FORCE™ platform, Dyne is developing modern oligonucleotide therapeutics that are designed to overcome limitations in delivery to muscle tissue seen with other approaches. Dyne has a broad portfolio of therapeutic candidates for serious muscle diseases, including myotonic dystrophy type 1 (DM1), Duchenne muscular dystrophy (DMD) and facioscapulohumeral muscular dystrophy (FSHD). For more information, please visit https://www.dyne-tx.com/, and follow us on Twitter, LinkedIn and Facebook.

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 Dyne's strategy, future operations, prospects and plans, objectives of management, the potential of the FORCE platform, the expected timeline for submitting its response to the FDA's clinical hold letter, submitting investigational new drug applications and dosing patients in trials and the anticipated design of the trials, 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. Dyne 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; uncertainties as to the timing of and Dyne's ability to submit and obtain regulatory clearance for investigational new drug applications and initiate clinical trials, including with respect to its response to the DYNE-251 clinical hold letter and its ability to obtain regulatory clearance of the DYNE-251 IND; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; whether investigators and regulatory agencies will agree with the design of Dyne's planned clinical trials; whether Dyne'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 COVID-19 pandemic on Dyne's business and operations; as well as the risks and uncertainties identified in Dyne's filings with the Securities and Exchange Commission (SEC), including the Company's most recent Form 10-Q and in subsequent filings Dyne may make with the SEC. In addition, the forward-looking statements included in this press release represent Dyne's views as of the date of this press release. Dyne anticipates that subsequent events and developments will cause its views to change. However, while Dyne 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 Dyne's views as of any date subsequent to the date of this press release.

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