Dyne Therapeutics Announces Clearance of Clinical Trial Application for DYNE-101 for the Treatment of Myotonic Dystrophy Type 1

- Initiation of Patient Dosing in Multiple Ascending Dose Clinical Trial of DYNE-101 On Track for Mid-2022 -

- Executing on Global Clinical and Regulatory Strategy: Clinical Trial Application Cleared in New Zealand and Additional Clearances Expected in Multiple Countries -

WALTHAM, Mass., July 12, 2022 – Dyne Therapeutics, Inc. (Nasdaq: DYN), a clinical-stage muscle disease company focused on advancing innovative life-transforming therapeutics for people living with genetically driven diseases, today announced that the New Zealand Medicines and Medical Devices Safety Authority cleared its clinical trial application to initiate its multiple ascending dose (MAD) clinical trial of DYNE-101 in patients with myotonic dystrophy type 1. The Company also anticipates receiving regulatory clearance in additional countries for DYNE-101. Dyne expects to begin dosing patients in its Phase 1/2 clinical trial of DYNE-101 in mid-2022.

"We are pleased to have received our first regulatory clearance for DYNE-101, an important milestone in our efforts to execute our planned global clinical trial for people living with DM1. In addition, we have aligned on the clinical trial design, including our starting dose, with regulatory authorities in multiple countries, and we are focused on initiating the study. Today's DM1 update, coupled with the recent clearance of DYNE-251 for DMD by FDA, furthers our commitment to bring our co-lead programs to patients in the clinic in mid-2022," said Joshua Brumm, president and chief executive officer of Dyne. "We thank the New Zealand Medicines and Medical Devices Safety Authority, FDA and other global regulatory authorities for their partnership as we continue to advance our mission of delivering life-transforming therapies for people with serious muscle diseases."

Dyne plans to evaluate DYNE-101 in a global, randomized, placebo-controlled, multiple ascending dose (MAD) clinical trial with a long-term extension study. The trial aims to enroll approximately 60 to 70 adult patients with DM1. The study will evaluate safety, tolerability, splicing index, pharmacokinetics and pharmacodynamics, and measures of muscle strength and function. Dyne plans to outline additional details regarding the trial design and timing of data upon initiation of dosing.

About Myotonic Dystrophy Type 1 (DM1)

DM1 is a rare, progressive, genetic disease that affects skeletal, cardiac and smooth muscle. It is a monogenic, autosomal dominant disease caused by an abnormal trinucleotide expansion in a region of the *DMPK* gene. This expansion of CTG repeats causes toxic RNA to cluster in the nucleus, forming nuclear foci and altering the splicing of multiple proteins essential for normal cellular function. This altered splicing results in a wide range of symptoms. People living with DM1 typically experience progressive weakness of major muscle groups, which can affect mobility, breathing,

heart function, speech, digestion and vision as well as cognition. DM1 is estimated to affect more than 40,000 people in the United States and over 74,000 people in Europe, but there are currently no approved disease-modifying therapies.

About DYNE-101

DYNE-101 is Dyne's product candidate being developed for people living with myotonic dystrophy type 1 (DM1). DYNE-101 consists of an antigen-binding fragment antibody (Fab) conjugated to an antisense oligonucleotide (ASO) to enable targeted muscle tissue delivery with the goal of reducing toxic *DMPK* RNA in the nucleus, releasing splicing proteins, allowing normal mRNA processing and translation of normal proteins, and potentially stopping or reversing the disease. Dyne has generated comprehensive preclinical data supporting its DM1 program, including reduction of nuclear foci and correction of splicing in patient cells, robust knockdown of toxic human nuclear *DMPK* RNA and correction of splicing in a novel *in vivo* model developed by Dyne, reversal of myotonia after a single dose in a disease model, and enhanced muscle distribution as evidenced by significant reduction in wild-type *DMPK* RNA in non-human primates.

About Dyne Therapeutics

Dyne Therapeutics is a clinical-stage muscle disease company focused on 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 programs for serious muscle diseases, including candidates for 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 anticipated timelines for dosing patients in the DYNE-251 trial and the DYNE-101 trial and the planned trial design of the DYNE-101 trial and the status of other regulatory submissions for the DYNE-101 trial, 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 initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; the timing of and Dyne's ability to obtain regulatory authorization, initiate and enroll patients in clinical trials; whether results from preclinical studies will be predictive of the results of later preclinical studies and 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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