



Dyne Therapeutics Highlights Preclinical Data and Clinical Development Plans for DMD and DM1 Programs at Inaugural R&D Day

October 13, 2021

- Investigational New Drug (IND) Submissions Anticipated for DYNE-251 in DMD During the Fourth Quarter of 2021 and for DYNE-101 in DM1 During the First Quarter of 2022 -

- Event also Features Presentations and Commentary by Leading Neuromuscular Disease Experts, Valeria Sansone, M.D., Ph.D. and John Day, M.D., Ph.D. -

WALTHAM, Mass., Oct. 13, 2021 (GLOBE NEWSWIRE) -- [Dyne Therapeutics, Inc.](https://investors.dyne-tx.com/events/event-details/dyne-rd-day) (Nasdaq: DYN), a muscle disease company focused on advancing innovative life-transforming therapeutics for people living with genetically driven diseases, hosts its first Research and Development Day today focused on the Company's co-lead development programs for rare muscle diseases, Duchenne muscular dystrophy (DMD) and myotonic dystrophy type 1 (DM1). "The Muscle to Move to the Clinic" live virtual event (8:00-10:30 a.m. ET) as well as the replay and slide presentation are available at <https://investors.dyne-tx.com/events/event-details/dyne-rd-day>.

"We are thrilled to host our inaugural R&D Day a little more than a year after our IPO, and just two and a half years after announcing the launch of Dyne and our focus on building the world's leading muscle disease company. Today we will share that we plan to submit INDs for DYNE-251 in DMD during the fourth quarter of 2021 and for DYNE-101 in DM1 during the first quarter of 2022, with the intention of initiating global, placebo-controlled trials evaluating safety, key disease markers and muscle function in patients," said Joshua Brumm, President and Chief Executive Officer of Dyne. "Dr. Sansone and Dr. Day are recognized leaders in the field of neuromuscular disease, and we are grateful to them for sharing their expertise during the event and informing our programs. People living with DMD are underserved by current therapies and individuals with DM1 have no approved treatment options, so we feel a tremendous sense of urgency for the rare muscle disease community and are excited to advance these programs to the clinic."

The R&D Day program includes presentations and discussion with the following speakers, along with introductory remarks from Mr. Brumm:

- Presentations and commentary from Dr. Sansone, who is the Clinical and Scientific Director at Clinical Center NeMO and Associate Professor of Neurology at University of Milan; and Dr. Day, who serves as Professor of Neurology and Pediatrics and Director of the Neuromuscular Division at Stanford Neuroscience Health Center.
- Oxana Beskrovnaya, Ph.D., Dyne's Chief Scientific Officer, reviews [recent *in vivo* data presented](#) during the World Muscle Society 2021 Virtual Congress on the DM1 program and during the 2021 Muscle Study Group Annual Scientific Meeting on the DMD program, which provide strong support for the planned IND submissions.
- Wildon Farwell, M.D., MPH, Dyne's Chief Medical Officer, outlines preparations for advancing both programs into the clinic and initial plans for clinical trials, which will be finalized following review with investigators and regulators. For its DMD program, Dyne intends to initiate a global, placebo-controlled, multiple-ascending dose (MAD) clinical trial to evaluate DYNE-251 in patients with mutations amenable to exon 51 skipping. The Company also intends to initiate a global, placebo-controlled, MAD clinical trial evaluating DYNE-101 in adult patients with DM1.
- While the R&D Day event is focused on Dyne's co-lead programs, the Company also noted that it expects to submit an IND for DYNE-301 in facioscapulohumeral muscular dystrophy (FSHD) in the second half of 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's broad portfolio of therapeutic candidates for serious muscle diseases includes programs 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 expected timeline for submitting investigational new drug applications and 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; the timing of and Dyne's ability to submit and obtain regulatory clearance for investigational new drug applications; 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.

Contact:

Dyne Therapeutics
Amy Reilly
areilly@dyne-tx.com
857-341-1203