Dyne Therapeutics Highlights DM1 and DMD Clinical Programs During “Spotlight on the Clinic” Virtual Event

September 12, 2022

- Presentation and Discussion with Two Leading Neuromuscular Disease Experts -

- Data from DYNE-101 ACHIEVE and DYNE-251 DELIVER Clinical Trials Anticipated in the Second Half of 2023 -

- Refined Focus on Lead Clinical Programs Extending Cash Runway Through 2024 -

WALTHAM, Mass., Sept. 12, 2022 (GLOBE NEWSWIRE) -- 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 hosts a virtual event, “Spotlight on the Clinic," highlighting its clinical programs, DYNE-101 in myotonic dystrophy type 1 (DM1) and DYNE-251 in Duchenne muscular dystrophy (DMD) from 7:30-9:00 a.m. ET. Speakers include neuromuscular disease experts, Valeria Sansone, M.D., Ph.D., Clinical and Scientific Director at Clinical Center NeMO; and Professor of Neurology, University of Milan, Richard Finkel, M.D., Director of the Center for Experimental Neurotherapeutics at St. Jude Children’s Research Hospital, as well as members of Dyne’s leadership team. The live virtual event as well as the replay and slide presentation are available at https://investors.dyne-tx.com/events/event-details/dyne-spotlight-clinic-virtual-event.

“With our DYNE-251 and DYNE-101 clinical trials now underway, this is a very exciting time for Dyne and people living with DMD and DM1. DELIVER and ACHIEVE, which are both designed to be registrational trials, are expected to report data in the second half of 2023, including evaluating important biomarkers of dystrophin in DMD and splicing in DM1,” said Joshua Brumm, president and chief executive officer of Dyne. “We are extremely grateful to Drs. Sansone and Finkel for sharing their insights today, including on the unmet needs of their patients and where new therapies have the potential to address diseases with no or limited treatment options.”

In addition to remarks and discussion with the neuromuscular disease experts, the event includes a review of Dyne’s clinical programs and pipeline:

- **DELIVER Trial in DMD**: Patient dosing is underway in DELIVER, a Phase 1/2 global clinical trial evaluating DYNE-251 for the treatment of DMD mutations amenable to exon 51 skipping. The DELIVER trial consists of a 24-week multiple ascending dose (MAD) randomized, placebo-controlled period, a 24-week open-label extension and a 96-week long-term extension. The trial, which is designed to be registrational, is expected to enroll approximately 46 ambulant and non-ambulant males with DMD who are ages 4 to 16 and have mutations amenable to exon 51 skipping therapy. The primary endpoints are safety, tolerability and change from baseline in dystrophin levels as measured by Western blot. Secondary endpoints include measures of muscle function, exon skipping and pharmacokinetics. Data from the MAD placebo-controlled portion of the DELIVER trial on safety, tolerability and dystrophin are anticipated in the second half of 2023.
- **ACHIEVE Trial in DM1 –** Dyne has initiated its ACHIEVE trial evaluating DYNE-101 for the treatment of DM1. The ACHIEVE trial is a Phase 1/2 global clinical trial consisting of a 24-week MAD randomized, placebo-controlled period, a 24-week open-label extension and a 96-week long-term extension. The trial, which is designed to be registrational, is expected to enroll approximately 64 adult patients with DM1 who are 18 to 49 years of age. The primary endpoints are safety and tolerability; secondary endpoints include pharmacokinetics and pharmacodynamics, including change from baseline in splicing, as well as measures of muscle strength and function. Data from the MAD placebo-controlled portion of the ACHIEVE trial on safety, tolerability and splicing are anticipated in the second half of 2023.
- **Pipeline and Resources**: Dyne is prioritizing its focus and resources on its clinical programs, DYNE-101 in DM1 and DYNE-251 in DMD. The Company remains committed to advancing its facioscapulohumeral muscular dystrophy (FSHD) program but is deferring the Investigational New Drug application submission for DYNE-301 originally targeted for the second half of 2022. As a result, Dyne expects its cash runway will be extended through 2024 and plans to provide an update on its FSHD program in 2023.

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-101 trial and for reporting data from the

DYNE-251 and DYNE-101 clinical trials, the trial design of the DYNE-251 and DYNE-101 clinical trials, the expected timeline for submitting an investigational new drug application for Dyne's FSHD program and the sufficiency of Dyne's existing cash resources for the period anticipated, 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 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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