Dyne Therapeutics to Host Virtual Investor Event to Review New Clinical Data from the ACHIEVE and DELIVER Trials Tomorrow, May 20 at 8:00 a.m. ET

May 19, 2024

WALTHAM, Mass., May 19, 2024 (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 announced it now plans to report new efficacy and safety data from its Phase 1/2 ACHIEVE and DELIVER clinical trials on May 20, 2024, and to host a virtual event at 8:00 a.m. ET. This represents an update to Dyne's prior guidance for the second half of 2024. The company intends to issue a press release prior to the start of the event.

Phase 1/2 ACHIEVE Trial of DYNE-101 in DM1

- ACHIEVE is a Phase 1/2 global clinical trial evaluating DYNE-101 in adult patients with myotonic dystrophy type 1 (DM1) who are 18 to 49 years of age. ACHIEVE, which is designed to be a registrational trial, consists of a 24-week multiple ascending dose (MAD), randomized, placebo-controlled period, a 24-week open-label extension (OLE) and a 96-week long-term extension (LTE). Enrollment is complete through the 6.8 mg/kg (approximate ASO dose) cohort evaluating once every eight-week dosing. A total of 56 patients have been enrolled in the study with approximately 500 doses administered to date.

- In the upcoming clinical update, Dyne plans to report safety and tolerability data from all enrolled cohorts. Additionally, pharmacokinetic and pharmacodynamic data, including change from baseline in splicing, measures of muscle strength and function, and patient reported outcomes will be shared. Efficacy data will be shared from the 1.8 mg/kg Q4W cohort (n=16) at 12 months, 3.4 mg/kg Q4W cohort (n=16) at 6 months, and 5.4 mg/kg Q8W cohort (n=8) at 3 months.

Phase 1/2 DELIVER Trial of DYNE-251 in DMD

- DELIVER is a Phase 1/2 global clinical trial evaluating DYNE-251 in ambulant and non-ambulant males with Duchenne muscular dystrophy (DMD) who are ages 4 to 16 and have mutations amenable to exon 51 skipping. DELIVER, which is designed to be a registrational trial, consists of a 24-week MAD, randomized, placebo-controlled period, a 24-week OLE and a 96-week LTE. Enrollment is complete through the 40 mg/kg (approximate PMO dose) cohort evaluating once every eight-week dosing. A total of 48 patients have been enrolled in the study with approximately 480 doses administered to date.

- In the upcoming clinical update, Dyne plans to report safety and tolerability data from all enrolled cohorts. Additionally, pharmacokinetic and pharmacodynamic data, including dystrophin expression measured by Western blot, will be shared from the 10 mg/kg Q4W cohort (n=8) at 6 months.

Virtual Investor Event

The live event webcast will be available on the Events & Presentations page of the Investors & Media section of Dyne's website and a replay will be accessible for 90 days following the presentation. An accompanying slide presentation will also be available. To register for the live webcast and replay, please visit https://investors.dyne-tx.com/news-and-events/events-and-presentations.

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. Dyne has a broad pipeline for serious muscle diseases, including clinical programs for myotonic dystrophy type 1 (DM1) and Duchenne muscular dystrophy (DMD) and a preclinical program for facioscapulohumeral muscular dystrophy (FSHD). For more information, please visit https://www.dyne-tx.com/, and follow us on X, LinkedIn and Facebook.

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