Dyne Therapeutics Announces New Positive Cardiopulmonary Results from DELIVER Trial of Z-Rostudirsen in Duchenne Muscular Dystrophy (DMD)

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- New analyses out to 24-months showed improvement in heart and lung function compared to expected declines in DMD natural history -

- Data expand on previously reported results demonstrating that z-rostudirsen treatment led to sustained functional improvement across multiple clinical measures -

WALTHAM, Mass., March 08, 2026 (GLOBE NEWSWIRE) -- Dyne Therapeutics, Inc. (Nasdaq: DYN), a clinical-stage company focused on delivering functional improvement for people living with genetically driven neuromuscular diseases, today announced additional positive data from the ongoing Phase 1/2 DELIVER clinical trial of zeleciment rostudirsen (z-rostudirsen, also known as DYNE-251), in individuals with Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping. These data are being presented in a late-breaking poster presentation at the 2026 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference being held March 8-11, 2026, in Orlando, FL, which is available in the Scientific Publications & Presentations section of Dyne's website along with all of Dyne's other posters being presented at the conference.

"This week we are presenting additional analyses of 24-month data from the DELIVER trial showing the breadth of potential benefits z-rostudirsen may bring to individuals with exon 51 skip amenable DMD beyond the previously reported unprecedented improvements in muscle function," said Doug Kerr, M.D., Ph.D., chief medical officer of Dyne. "Cardiopulmonary issues are a key area of concern in DMD, so we are particularly encouraged by new analyses showing improvement in both heart and lung function out to 24 months. We attribute these results to the differentiated capabilities of our FORCE platform to deliver therapeutics to a broad range of muscles, including the heart, trunk and diaphragm, as well as the CNS."

Dyne announced the results of new analyses of cardiac and pulmonary function amongst all DELIVER participants who were randomized to z-rostudirsen treatment at baseline (any dose[1]) and for whom cardiac magnetic resonance imaging and/or pulmonary function data were available.

- Improvement from baseline in lung function, as measured by Forced Vital Capacity Percent Predicted (FVC%p), was observed through 24 months, as compared to the expected decline estimated in published natural history data[2-4].
- Improvement from baseline was observed through 24 months in circumferential strain, an early signal of cardiac performance, as compared to the expected worsening estimated in published natural history data[5,6].
- Improvement from baseline in left ventricular ejection fraction, a measure of how well the heart is pumping, was observed at 24 months, in contrast with the expected decline estimated in published natural history data[5,6].
- In previously reported safety and tolerability data from 86 total participants enrolled in the DELIVER trial and followed for up to 36 months, z-rostudirsen demonstrated a favorable safety profile[7], and most related treatment emergent adverse events (TEAEs) were mild or moderate. The most commonly reported related TEAEs were pyrexia (fever) and headache. No related serious TEAEs were observed in the REC.

These data will be presented in a poster titled "Zeleciment rostudirsen led to trends in long-term improvement in clinical outcomes including cardiopulmonary function: Additional data from DELIVER" (poster # 476 LBT).

About the DELIVER Trial
DELIVER is a global, randomized, placebo-controlled, double-blind, Phase 1/2 clinical trial that evaluated the safety, tolerability and efficacy (as measured by both biomarker and functional improvement) of zeleciment rostudirsen (z-rostudirsen, also known as DYNE-251) in individuals with Duchenne muscular dystrophy (DMD) who have mutations in the DMD gene that are amenable to exon 51 skipping. The multiple ascending dose (MAD) portion of the study resulted in the selection of a registrational dose and regimen of 20 mg/kg of z-rostudirsen administered every four weeks. The placebo-controlled portion of the registrational expansion cohort (REC) to support a potential regulatory submission for U.S. Accelerated Approval has been completed. The primary endpoint for this cohort was the change from baseline in dystrophin protein levels as measured by Western blot at 6 months. Participants from the MAD and REC portions had the option to enroll in the open-label extension and long-term extension portions of the study. For more information on the DELIVER trial, visit clinicaltrials.gov and euclinicaltrials.eu.

About zeleciment rostudirsen (z-rostudirsen, also known as DYNE-251)
Z-rostudirsen is an investigational therapeutic being evaluated in the Phase 1/2 global DELIVER clinical trial for individuals with DMD who have mutations in the DMD gene that are amenable to exon 51 skipping. Z-rostudirsen consists of a phosphorodiamidate morpholino oligomer (PMO) conjugated to an antigen-binding fragment (Fab) that binds to the transferrin receptor 1 (TfR1). It is designed to enable the production of near full-length dystrophin in muscle and the central nervous system (CNS) to provide functional improvement. Z-rostudirsen has received Breakthrough Therapy, Fast Track and Rare Pediatric Disease designations from the U.S. Food and Drug Administration (FDA), as well as Orphan Drug designation from the FDA and European Medicines Agency (EMA) and the Ministry of Health, Labour and Welfare (MHLW) in Japan for the treatment of individuals with DMD amenable to exon 51 skipping.

In addition to z-rostudirsen, Dyne is building a DMD franchise and has preclinical programs targeting other exons, including DYNE-253, DYNE-245, DYNE-244 and DYNE-255.

About Duchenne Muscular Dystrophy (DMD)
Duchenne muscular dystrophy (DMD) is a rare X-linked progressive neuromuscular disorder caused by mutations in the DMD gene. These mutations result in a complete or near-complete absence of dystrophin, a protein critical for maintaining muscle structure and function. DMD is the most common form of childhood-onset muscular dystrophy, affecting approximately 12,000 individuals in the U.S. and 16,000 in the EU. Symptoms typically emerge between ages 3 and 5, beginning with muscle weakness in the upper arms, thighs and pelvic region, and progressively impacting the lower limbs, forearms, neck and trunk. In addition to physical decline, individuals may experience cognitive impairment and neuropsychiatric challenges such as intellectual disabilities, learning difficulties and behavioral disorders. Despite existing therapies, there remains a significant unmet need for new treatment options that deliver functional improvement.

About Dyne Therapeutics
Dyne Therapeutics is focused on delivering functional improvement for people living with genetically driven neuromuscular diseases. We are developing therapeutics that target muscle and the central nervous system (CNS) to address the root cause of disease. The company is advancing clinical programs for Duchenne muscular dystrophy (DMD) and myotonic dystrophy type 1 (DM1) as well as preclinical programs for facioscapulohumeral muscular dystrophy (FSHD), Pompe disease and multiple DMD mutations. At Dyne, we are on a mission to deliver functional improvement for individuals, families and communities. Learn more at https://www.dyne-tx.com/, and follow us on X, 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 clinical potential of zeleciment rostudirsen (z-rostudirsen, also known as DYNE-251) and its potential cardiopulmonary effects, and expectations regarding the availability of accelerated approval pathways for z-rostudirsen, 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," "will" 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; whether results from preclinical studies and initial data from clinical trials will be predictive of the final results of the clinical trials or future trials; uncertainties as to the FDA's and other regulatory authorities' interpretation of the data from Dyne's clinical trials and the regulatory approval process; whether Dyne's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; 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-K 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.

1. The majority of participants at the 24M timepoint initiated treatment at the 0.7–2.8 mg/kg Q4W dose levels. Because most participants accrued substantial time on doses lower than the registrational dose of 20 mg/kg z-rostudirsen Q4W, the observed long-term efficacy potentially does not reflect the effect of continuously maintaining 20 mg/kg Q4W.
2. Meier T, et al. Neuromuscul Disord. 2017;27(4):307–314
3. Mayer OH, et al. Pediatr Pulmonol. 2015;50(5):487–494
4. McDonald CM, et al. Neuromuscul Disord. 2018;28(11):897–909;
5. Batra A, et al. BMC Cardiovasc Disord. 2022;22(1):260;
6. Hagenbuch SC, et al. Am J Cardiol. 2010;105(10):1451–1455;
7. Z-rostudirsen (DYNE-251) safety data as of August 19, 2025.

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