Dyne Therapeutics to Present Additional One-Year Clinical Data from Phase 1/2 ACHIEVE Trial of Z-Basivarsen (DYNE-101) for Myotonic Dystrophy Type 1 (DM1) at Upcoming Medical Meetings

September 8, 2026

- Data from a pooled dose group of participants initially enrolled in the multiple ascending dose portion of the trial to be compared against a matched natural history cohort -

- Dyne also intends to provide the mean baseline value for video hand opening time (vHOT) in the ACHIEVE registrational expansion cohort (REC) in conjunction with these presentations -

- Topline data from the ACHIEVE REC are on track for Q1 2027 -

WALTHAM, Mass., Sept. 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 that it will present additional one-year clinical data from the Phase 1/2 ACHIEVE trial of zeleciment basivarsen (z-basivarsen, also known as DYNE-101) for DM1 at the 31st Annual International Congress of the World Muscle Society (WMS) being held September 29, 2026, through October 3, 2026, virtually and in Hiroshima, Japan, as well as the 2026 Annual Meeting of the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) being held September 29, 2026, through October 2, 2026, virtually and in Orlando, Florida.

These presentations will both include:

- Data at 6 and 12 months from a pooled dose group (N=25-26), comprised of participants initially enrolled in the 3.4 mg/kg Q4W, 5.4 mg/kg Q8W and 6.8 mg/kg Q8W cohorts of the multiple ascending dose (MAD) portion of the ACHIEVE trial, including participants originally assigned to placebo in these cohorts.
- Data at 12 months from a cohort of participants (N=41-46) from the ongoing END-DM1 natural history study who were propensity-matched to the ACHIEVE pooled dose group.
- Updated safety data from ACHIEVE MAD participants.

In conjunction with these presentations, Dyne will also provide the average baseline value for vHOT in the REC of the ACHIEVE trial (n=71), which remains blinded to treatment assignment. Topline data from the ACHIEVE REC are planned for Q1 2027.

WMS Presentation Details

The new data from ACHIEVE will be included in the oral presentation below:

Oral Presentation Title: Long-term functional improvement with zeleciment basivarsen in the phase 1/2 ACHIEVE trial
Presentation Date and Time: Wednesday, September 30, 12:30-12:45 p.m. JST (Tuesday, September 29, 11:30-11:45 p.m. ET)
Presenter: Karlien Mul, M.D., Ph.D., Radboud University Medical Centre

The slides from this presentation will be available in the Scientific Publications & Presentations section of Dyne's website.

Additional encore presentations at WMS include:

Poster Presentation Title: HARMONIA study design: A global phase 3 trial assessing the efficacy and safety of z-basivarsen in myotonic dystrophy type 1 (DM1)
Poster Session Date and Time: Friday, October 2, 3:45-4:45 p.m. JST

Poster Presentation Title: Zeleciment rostudirsen increased dystrophin protein levels and demonstrated functional improvement in clinical measures in the DELIVER trial
Poster Session Date and Time: Wednesday, September 30, 5:15-6:15 p.m. JST

Poster Presentation Title: FORZETTO, a phase 3 study of z-rostudirsen in ambulatory males with DMD mutations amenable to exon 51 skipping
Poster Session Date and Time: Wednesday, September 30, 5:15-6:15 p.m. JST

AANEM Presentation Details

The new data from ACHIEVE will be included in the poster presentation below:

Poster Presentation Title: Zeleciment basivarsen targets the underlying cause of myotonic dystrophy type 1 to enable functional improvement in the Phase 1/2 ACHIEVE trial
Poster Session Date and Time: Wednesday, September 30, 6:15-6:45 p.m. ET and Thursday, October 1, 9:30-10:00 a.m. ET

This poster presentation will be available in the Scientific Publications & Presentations section of Dyne's website.

Additional encore presentations at AANEM will include:

Poster Presentation Title: HARMONIA study design: A global Phase 3 trial assessing the efficacy and safety of z-basivarsen in myotonic dystrophy

type 1
Poster Session Date and Time: Wednesday, September 30, 6:15-6:45 p.m. ET and Thursday, October 1, 9:30-10:00 a.m. ET
Note: This abstract will also be featured in the Industry-Supported Research Highlights session on Wednesday, September 30, 1:45-1:53 p.m. ET

Poster Presentation Title: Zeleciment rostudirsen significantly increased dystrophin protein levels and led to functional improvement in clinical measures in the DELIVER trial
Poster Session Date and Time: Wednesday, September 30, 6:15-6:45 p.m. ET and Thursday, October 1, 9:30-10:00 a.m. ET

Poster Presentation Title: Zeleciment rostudirsen led to trends in long-term improvement in clinical outcomes including cardiopulmonary function
Poster Session Date and Time: Wednesday, September 30, 6:15-6:45 p.m. ET and Thursday, October 1, 2:45-3:15 p.m. ET

About the ACHIEVE Trial

ACHIEVE is a global, randomized, placebo-controlled, double-blind, Phase 1/2 clinical trial evaluating the safety, tolerability and efficacy of zeleciment basivarsen (z-basivarsen, also known as DYNE-101) in patients with myotonic dystrophy type 1 (DM1). The multiple ascending dose (MAD) portion of the study resulted in the selection of a registrational dose and regimen of 6.8 mg/kg z-basivarsen administered every eight weeks. A registrational expansion cohort to support potential regulatory submissions, including Accelerated Approval in the U.S., is fully enrolled. The primary endpoint for this cohort is the change from baseline in middle finger myotonia as measured by video hand opening time (vHOT) at 6 months, compared to placebo. For more information on the ACHIEVE trial, visit www.clinicaltrials.gov (NCT05481879) and euclinicaltrials.eu (EUCT2023-510353-42-00).

About Zeleciment Basivarsen (z-basivarsen, also known as DYNE-101)

Z-basivarsen is an investigational therapeutic being evaluated in the fully enrolled global Phase 1/2 ACHIEVE clinical trial and the global confirmatory Phase 3 HARMONIA clinical trial for people living with DM1. Z-basivarsen consists of an antisense oligonucleotide (ASO) conjugated to an antigen-binding fragment (Fab) that binds to the transferrin receptor 1 (TfR1) to enable delivery to muscle and the central nervous system. It is designed to deliver functional improvement in individuals living with DM1 by reducing toxic nuclear *DMPK* RNA to release splicing proteins and allow normal mRNA processing. Z-basivarsen has been granted Breakthrough Therapy, Orphan Drug and Fast Track designations by the U.S. Food and Drug Administration (FDA), as well as Orphan Drug designation from the European Medicines Agency (EMA) and the Ministry of Health, Labour and Welfare (MHLW) in Japan for the treatment of DM1.

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, and the therapeutic potential of zeleciment basivarsen (z-basivarsen, also known as DYNE-101), and the potential timing of the announcement of clinical data, including the baseline video hand-opening time of the ACHIEVE registrational expansion cohort (REC) and topline data from the REC, 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; the timing of and Dyne's ability to enroll patients in clinical trials; whether results from preclinical studies and initial data from early clinical trials will be predictive of the final results of the clinical trials or future trials or longer-term performance than is measured in the clinical trial; uncertainties as to the FDA's and other regulatory authorities' interpretation of the data from Dyne's clinical trials and acceptance of Dyne's clinical programs and the regulatory approval process, including the availability of accelerated approval pathways; 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-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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