Dyne Therapeutics Announces Completion of Enrollment in Registrational Expansion Cohort of ACHIEVE Trial of Z-Basivarsen for Myotonic Dystrophy Type 1 (DM1)

June 3, 2026

- Registrational expansion cohort enrolled 71 participants; topline data planned for Q1 2027 -

WALTHAM, Mass., June 03, 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 the completion of enrollment in the registrational expansion cohort (REC) of the Phase 1/2 ACHIEVE trial of zeleciment basivarsen (z-basivarsen, also known as DYNE-101) in individuals with DM1.

“Completing enrollment in the registrational expansion cohort of ACHIEVE is a critical milestone as we advance a potentially best-in-class therapy designed to address the multi-system nature of DM1,” said Doug Kerr, M.D., Ph.D., chief medical officer of Dyne. “With data from this cohort expected in the first quarter of next year, we believe we are well positioned to show a significant improvement in myotonia and trends on important functional outcomes to support a potential submission for U.S. Accelerated Approval. We expect that the strong interest we have seen in z-basivarsen will support enrollment in the ongoing confirmatory Phase 3 HARMONIA trial.”

Key Milestones for Z-Basivarsen

- Topline data from the ACHIEVE REC are planned for Q1 2027 to support a potential Biologics License Application (BLA) submission for U.S. Accelerated Approval in Q3 2027.
    - Dyne intends to use data from the REC and from the already enrolled participants in the multiple ascending dose (MAD) and ongoing long-term extension portions of the ACHIEVE trial to support a potential submission for Accelerated Approval in the U.S.
- Dyne expects a potential U.S. launch of z-basivarsen in H1 2028, assuming FDA grants Priority Review and approval is received on the anticipated timeline.
- Dyne also continues to pursue approval pathways outside of the U.S. for z-basivarsen in DM1.

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 Myotonic Dystrophy Type 1 (DM1)

Myotonic dystrophy type 1 (DM1) is a rare, progressive, genetic neuromuscular disease with high morbidity and early mortality. DM1 affects ~40,000 people in the U.S. and ~55,000 people in the EU. The severity of symptoms and rate of progression varies. Symptoms can begin at any point in an affected person’s life, depending on the DM1 subtype. Adult-onset DM1 symptoms typically appear between 20 to 40 years of age. DM1 is caused by mutations in the *DMPK* gene, leading to a widespread disruption of RNA splicing, known as spliceopathy, which drives the multi-system manifestations of the disease. People experience a broad spectrum of symptoms, including: muscle weakness throughout the body, myotonia or difficulty relaxing muscles, excessive daytime sleepiness, fatigue, dysregulated sleep, cognitive impairments, cardiac arrhythmias, respiratory issues and gastrointestinal dysfunction. Although the genetic cause of DM1 is well understood, there are currently no approved disease-modifying treatments for 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, the clinical potential of zeleciment basivarsen (z-basivarsen, also known as DYNE-101) and potential outcomes of the ACHIEVE trial, the timing of planned data from the registrational expansion cohort, the content and timing of the planned submission of a Biologics License Application for U.S. Accelerated Approval and potential for the U.S. Food and Drug Administration to grant Accelerated Approval, the ability to support enrollment of the confirmatory Phase 3 HARMONIA trial, the timing and potential of U.S. launch of z-basivarsen for myotonic dystrophy type 1, 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, completion and success 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; uncertainties as to the results of the Company's clinical trials, whether they will support regulatory submissions and the timing of regulatory submissions; uncertainties as to the FDA's and other regulatory authorities' interpretation of the data from Dyne's clinical trials 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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