November 4, 2026

# Definium Therapeutics Presents Topline Phase 3 Data for DT120 ODT in Generalized Anxiety Disorder and Major Depressive Disorder at 2026 NEI Fall Congress

*First-ever comprehensive presentation of DT120 clinical program to date including positive topline data from Panorama, Emerge and Voyage Phase 3 studies*

*New robust compilation of safety data across the three Phase 3 studies also to be presented*

NEW YORK--(BUSINESS WIRE)-- Definium Therapeutics, Inc. (Nasdaq: DFTX) (“Definium” or the “Company”), a late-stage clinical biopharmaceutical company developing a new generation of therapeutics intended to address underlying causes of psychiatric and neurological disorders, today announced four poster presentations at the 2026 NEI Fall Congress taking place November 5 through 8 in Colorado Springs, CO.

Positive topline results from Panorama, the Company’s second Phase 3 study of DT120 (lysergide) Orally Disintegrating Tablet (ODT) in adults with generalized anxiety disorder (GAD), will be shared for the first time at a medical congress. In addition, Definium will provide an overview of the DT120 Phase 3 safety data, two encore presentations of positive topline data from Emerge in major depressive disorder (MDD), and positive topline data from Voyage in GAD.

“We look forward to sharing new data from our DT120 program with the psychiatric community at the NEI Fall Congress. These presentations will add to the growing body of evidence from our clinical development program in GAD and MDD, and support continued clinical assessment of DT120’s potential role in treating these conditions,” said Dan Karlin, MD, Chief Medical Officer, Definium Therapeutics.

All poster presentations will take place on Saturday, November 7$^{th}$ from 2:40-3:40 PM MDT.

Details of the poster presentations are below. Additional Congress activities include a sponsored Scientific Exchange oral presentation and Definium’s medical affairs booth located at #1100:

| Title | | Session Time and Location |
|---|---|---|
| Scientific Exchange Oral Presentation (sponsored) | | Friday, November 6<br>5:25-6:35 PM MDT<br>Rocky Mountain Ballroom |
| **Posters** | **Poster #** | **Session Time and Location** |
| DT120 (Lysergide) Demonstrated Statistically Significant Improvements in Adults With Generalized Anxiety Disorder in This Phase 3 Trial: Panorama | 157 | Saturday, November 7<br>2:40-3:40 PM MDT<br>Rocky Mountain Ballroom |
| Phase 3 Topline Results of DT120 (lysergide) in Major Depressive Disorder (Emerge) | 142 | Saturday, November 7<br>2:40-3:40 PM MDT<br>Rocky Mountain Ballroom |
| Phase 3 Topline Results of DT120 (Lysergide) in Generalized Anxiety Disorder (Voyage) | 158 | Saturday, November 7<br>2:40-3:40 PM MDT<br>Rocky Mountain Ballroom |
| DT120 (Lysergide) Safety From Phase 3 Studies in Major Depressive Disorder and Generalized Anxiety Disorder | 156 | Saturday, November 7<br>2:40-3:40 PM MDT<br>Rocky Mountain Ballroom |

## About Panorama

Panorama (MM120-301) is a Phase 3, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of DT120 ODT in adults with GAD. The study enrolled participants 18 to 74 years of age with a DSM-5-confirmed primary diagnosis of GAD and a minimum Hamilton Anxiety Rating Scale (HAM-A) total score of 20 at screening and baseline. Eligible participants were randomized 2:1:2 to receive a single dose of DT120 ODT 100 µg, DT120 ODT 50 µg, or matching placebo, with the 50 µg arm included to confound participants as to their allocation. The study consists of a 12-week double-blind treatment period (Part A) followed by a 40-week extension phase with opportunities for open-label treatment (Part B), during which participants may be eligible to receive up to four additional doses of DT120 ODT 100 µg based on symptom severity, for a total study duration of approximately 56 weeks. The primary endpoint was change from baseline in HAM-A total score at Week 12. Key secondary multiplicity-controlled endpoints were change from baseline in Clinical Global Impression-Severity (CGI-S) scale score at Week 12, change from baseline in HAM-A total score at Week 1, and change from baseline in CGI-S score at Day 2. Panorama enrolled 245 participants at approximately 32 study centers.

Panorama is the second Phase 3 study of DT120 ODT in adults with GAD and the third positive Phase 3 readout for DT120 ODT, following positive Emerge results in MDD and positive Voyage results in GAD.

## About Voyage

Voyage is a Phase 3, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of a single 100 µg dose of DT120 ODT versus placebo in adults with GAD. The study consists of a 12-week double-blind period (Part A) followed by a 40-week extension phase with opportunities for open-label treatment (Part B), during which

participants may be eligible to receive up to four additional doses of DT120 ODT based on symptom severity.

The study enrolled 214 participants aged 18 to 74 years across approximately 35 sites in the United States with a DSM-5-confirmed diagnosis of GAD, based on clinical assessment and the Mini-International Neuropsychiatric Interview (MINI), and a HAM-A score of at least 20 at screening and baseline.

The primary endpoint was change from baseline in HAM-A score at Week 12. Key secondary multiplicity-controlled endpoints were change from baseline in CGI-S scale score at Week 12, change from baseline in HAM-A total score at Week 1, and change from baseline in CGI-S score at Day 2.

Voyage is one of two pivotal Phase 3 studies in GAD.

**About Emerge**

Emerge is a Phase 3, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of a single 100 µg dose of DT120 ODT versus placebo in participants with MDD. The study consists of a 12-week double-blind phase (Part A) followed by a 40-week extension phase with opportunities for open-label treatment (Part B) during which participants may be eligible to receive DT120 ODT based on symptom severity.

The study enrolled 149 participants aged 18 to 74 years across 20 sites with a DSM-5-confirmed diagnosis of MDD, a Montgomery-Åsberg Depression Rating Scale (MADRS) total score of at least 26, and a CGI-S score of at least 4 at screening and baseline.

The primary endpoint was change from baseline in the MADRS total score at Week 6. Key secondary endpoints were change from baseline in CGI-S score at Week 6, Week 12, and Day 2, and change from baseline in MADRS total score at Week 12 and Week 1.

**About DT120 Orally Disintegrating Tablet (ODT)**

DT120 ODT is an ergoline derivative belonging to the group of classic serotonergic psychedelics, which acts as a partial agonist at 5-hydroxytryptamine serotonin-2A (5-HT2A) receptors. DT120 ODT is Definium's proprietary and pharmaceutically optimized formulation of Lysergide (LSD). DT120 ODT is an advanced formulation incorporating Catalent's Zydis® ODT fast-dissolve technology, designed to deliver several unique advantages, including faster absorption and onset of transient cognitive, perceptual, and affective changes, improved bioavailability, and a lower incidence of gastrointestinal side effects. Definium is developing DT120 ODT, the tartrate salt form of Lysergide, for generalized anxiety disorder (GAD), major depressive disorder (MDD), and posttraumatic stress disorder (PTSD), and is exploring its potential applications in other serious brain health disorders. DT120 has received Breakthrough Therapy designation from the FDA for GAD and MDD. Definium maintains a strong foundation to protect and extend the long-term value of the DT120 ODT franchise through a multi-layered intellectual property strategy spanning composition, formulation, and methods-of-use patents.

**About Lysergide (LSD)**

Lysergide (LSD) is one of the most extensively studied psychopharmaceuticals in history, with over 1,000 published reports.[1] First synthesized in 1938 by Swiss chemist Albert

Hofmann in his search for active principles from ergot fungus, its profound psychological effects were discovered in 1943, which transformed psychiatric research.[1] LSD, a definitional classic psychedelic, temporarily alters perception, cognition, and emotion, is physiologically safe and non-addictive, and is not associated with withdrawal.[1] While its precise mechanism of action in the treatment of psychiatric illness is unknown, its acute perceptual, cognitive, and affective effects are mediated by agonism of the serotonin 5-hydroxytryptamine 2A (5-HT2A) receptor, and mechanistic hypotheses suggest that it causes sustained increases in neuroplasticity in a variety of brain regions.[2,3]

**About Definium Therapeutics**

The mission of Definium Therapeutics is to forge a new era of psychiatry by applying scientific rigor to psychedelics, with the goal of developing accessible treatments that unlock healing at scale. Guided by a recognition that patients deserve more than better, Definium is relentlessly advancing a new generation of therapeutics intended to address underlying causes of psychiatric and neurological disorders. By turning evidence into impact, Definium aims to change the trajectory of today's mental health care crisis and enable a healthier future. Headquartered in New York, Definium Therapeutics trades on Nasdaq under the symbol DFTX.

For more information, visit https://definiumtx.com/ and follow Definium Therapeutics on Instagram, LinkedIn and X.

**References**

1. Nichols, DE. “Psychedelics.” Pharmacological Reviews. 2016;68(2):264-355.
2. Passie, T, Halpern, JH, Stichtenoth, DO, et al. “The Pharmacology of Lysergic Acid Diethylamide: A Review.” CNS Neuroscience & Therapeutics. 2008;14:295-314.
3. Liechti, ME. “Modern clinical research on LSD.” Neuropsychopharmacology. 2017;42:2114-2127.

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