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New Healthcare Claims Study Published in CNS Spectrums Finds High Rates of Treatment Switching, Discontinuation, and Prolonged Gaps in Care Among Patients with Generalized Anxiety Disorder (GAD)

Data highlight the challenges of achieving response and sustained remission in newly diagnosed and established GAD patients with existing therapies

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 the underlying causes of psychiatric and neurological disorders, today announced results from a new healthcare claims study of treatment patterns of newly diagnosed and established GAD patients, including pharmacotherapy use, discontinuation, switching and treatment progression. The findings, published in CNS Spectrums, highlight the challenges in achieving response and sustained remission with existing treatments and underscore the need for new GAD treatments that provide better efficacy, rapid onset, sustained symptom control, and improved tolerability.

The study highlights substantial unmet need in GAD treatment, revealing frequent treatment discontinuation, switching, and prolonged gaps in care that often occur well before the 6–12 months of therapy recommended in clinical guidelines to reduce relapse risk. Specifically, the analysis found:

- **55%** of newly diagnosed patients discontinued their initial pharmacotherapy, and **28%** added or switched treatment. Among established patients, **16%** discontinued and **55%** added or switched treatment.
- Treatment changes were rapid: newly diagnosed patients switched at a median of **31 days** and initiated combination therapy at **49 days**, whereas established patients switched at **42 days** and initiated combination therapy at **32 days**.
- Median time to discontinuation was **84 days** (newly diagnosed) and **119 days** (established), both shorter than recommended in clinical guidelines.
- **57%** of newly diagnosed patients who discontinued did not resume therapy during the study period. Among patients restarting after discontinuation, median treatment gap was **146 days** (newly diagnosed) and **96 days** (established).
- Among patients who modified their initial treatment, **75%** of newly diagnosed and **94%** of established patients experienced at least one additional therapy change within 12 months.

“GAD affects approximately 1 in 10 adults in the U.S., and our analysis shows that for many of them, current treatments simply aren’t delivering with many patients struggling to remain on treatment. More than half of newly diagnosed patients who stopped therapy never restarted during the study follow-up. We can’t close that gap without better options," said

Roger S. McIntyre, MD, FRCPC, co-author and Professor of Psychiatry and Pharmacology at the University of Toronto. “Behind every statistic is a person who has not achieved the symptomatic relief that’s meaningful for them, often leading them to stop treatment and providing impetus for us to discover innovative new treatments.”

“Our real-world data analysis revealed high rates of pharmacotherapy switching, discontinuation, and prolonged gaps in care among patients with GAD," said Derek Louie, PharmD, MS, lead author and Director of Health Outcomes and Economic Research at Definium Therapeutics. “These challenges are compounded by GAD's frequent co-occurrence with major depressive disorder, further complicating treatment management. Together, these findings underscore the urgent need for new treatment options that address both conditions.”

GAD remains one of the most common psychiatric disorders, characterized by excessive and persistent worry that can significantly impair daily functioning and quality of life. There has been little innovation in the treatment of GAD in the past several decades, with the last new drug approval occurring in 2007. Even with available treatment options, many patients do not achieve adequate or sustained symptom relief, and many experience adverse effects such as weight gain and sexual dysfunction, contributing to ongoing clinical and societal burden.[1-3]

Despite the substantial burden of GAD, treatment guidance remains fragmented. The absence of consensus-based algorithms creates uncertainty regarding when to initiate and how to sequence treatments. As of 2026, no formal comprehensive clinical practice guidelines for GAD exist in the U.S. Although the American Academy of Family Physicians previously developed a practice consensus for GAD and panic disorder, its recommendations for GAD management are limited. By evaluating treatment patterns among both newly diagnosed and established GAD patients, this analysis characterizes the evolution of pharmacologic management and provides real-world insights into the effectiveness and tolerability of current treatment strategies beyond data derived primarily from randomized controlled trials.

The authors note that an inherent limitation of claims analyses is that the data captured is restricted to information available in medical claims. Additionally, the analysis did not distinguish patients with GAD alone from those with comorbid psychiatric conditions, which may meaningfully influence treatment trajectories.

About the Study
This was a retrospective analysis of closed claims data from the Komodo Healthcare Map™ — a longitudinal, de-identified U.S. pharmacy and medical claims database comprising ~120 million patients across 150+ health plans, representative of the insured U.S. population. Adult patients with GAD (≥18 years) were identified using ICD-10 code F41.1, requiring ≥2 medical claims ≥30 days apart, or ≥1 claim plus ≥1 GAD-related pharmacotherapy claim, between January 1, 2020 and December 31, 2024. Two cohorts were defined: **newly diagnosed GAD** (n=259,158) and **established GAD** (n=1,018,288). Treatment patterns were assessed over 24 months across four categories: discontinuation, switch, combination, and persistence.

About Generalized Anxiety Disorder (GAD)
GAD is one of the most common psychiatric disorders, affecting approximately 26 million U.S. adults.[4,5] People with GAD experience constant, overwhelming worry that is hard to control. Common symptoms include fatigue, muscle tension, trouble concentrating, and

difficulty sleeping.[6] GAD often occurs alongside other health problems like chronic physical symptoms, depression, other anxiety disorders, and trauma-related conditions. Together, these issues can seriously impact a person's daily life, including substantial functional, economic, and quality-of-life burdens, and are associated with increased healthcare utilization and costs.[7-9]

While several GAD pharmacotherapies are approved, many patients do not experience sustained relief, and approximately 50% inadequately respond to first-line treatments.[10] Despite the significant personal and societal burden of GAD, there has been little innovation in the treatment of GAD in the past several decades, with the last new drug approval occurring in 2007.[11]

About Major Depressive Disorder (MDD)
Major Depressive Disorder (MDD) is the second-most common mental health disorder in the U.S., with over 21 million adults experiencing a major depressive episode (MDE) each year.[12,13] This disorder, a leading cause of disability worldwide,[14] brings persistent feelings of worthlessness, fatigue, and recurrent thoughts of death[15] while increasing long-term mortality risk by 40%.[16] MDD also carries a $326 billion annual economic burden in the U.S., driven by healthcare costs and lost productivity.[17] The MDD treatment paradigm is characterized by critical unmet needs, including fewer than one-third of patients reaching remission with first-line treatments[18], onset of clinical activity that takes weeks to months,[19,20] poor tolerability,[21,22] and frequent switching, augmentation, and discontinuation of pharmacotherapy.[23]

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.

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Investors:
Gitanjali Jain
VP, Head of Investor Relations
ir@definiumtx.com

Media:
media@definiumtx.com

Source: Definium Therapeutics, Inc.