FDA Grants Priority Review to Drug for Depressive Disorders

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The Alliance for Patient Access, founded in 2006, is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA accomplishes this mission by recruiting, training and mobilizing policy-minded physicians to be effective advocates for patient access. AfPA is organized as a non-profit 501(c)(4) corporation and headed by an independent board of di[1]rectors. Its physician leadership is supported by policy advocacy management and public affairs consultants.

In 2012, AfPA established the Institute for Patient Access, a related 501(c)(3) non-profit corporation. The Institute for Patient Access is a physician-led policy research organization dedicated to maintaining the primacy of the physician-patient relationship in the provision of quality health care. In furtherance of its mission, IfPA produces educational materials and programming designed to promote informed discussion about patient access to approved therapies and appropriate clinical care.

Visit allianceforpatientaccess.org and instituteforpatientaccess.org to learn more about each organization.

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However, doctors and hospitals currently overwhelmed by those seeking help might soon have a new tool to support people experiencing major depressive disorder and new mothers experiencing postpartum depression.

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Two-Week Treatment

The FDA recently granted zuranolone priority review. The status is reserved for medicines that, if approved, would significantly improve the effectiveness of treatment, diagnosis, or prevention of a serious condition. Under the priority review system, the FDA is scheduled to act on the application for this drug in early August. (1)

Zuranolone is being evaluated as a rapid-acting, 14-day oral treatment for adults with postpartum depression or major depressive disorder. Its reported ability to relieve symptoms in two weeks makes it a potentially game-changing option, as current medications can take several months to show results.

The drug itself is a neuroactive steroid. In people with depression, it works by rebalancing deregulated neuronal networks to help reset brain function. Zuranolone targets brain networks responsible for mood, arousal, behavior, and cognition, among other functions.

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An Increasing Burden

Rates of depressive disorders tripled early in the pandemic and continue to rise. It is estimated that 21 million adults in America experienced at least one major depressive episode in 2020, with nearly 14 million diagnosed with major depressive disorder.

Moreover, as many as one in seven new mothers in the U.S. experiences postpartum depression, totaling more than half a million