WICHITA, KANSAS – On March 5, the U.S. Food and Drug Administration approved esketamine as a breakthrough treatment for people with major depressive disorder.

“Breakthrough means it is a new treatment with a new mechanism for a major untreated medical need,” said Sheldon Preskorn, M.D., professor in the Department of Psychiatry & Behavioral Sciences at the University of Kansas School of Medicine-Wichita. “I believe esketamine is the first psychiatric treatment to receive this FDA designation.”

Preskorn is one of three physicians with ties to KU School of Medicine in Wichita and Kansas City who have played important roles in moving this drug toward FDA approval. He received his medical degree and completed a residency and internship in Kansas City. The research he completed at the medical school in Wichita stimulated interest in the glutamatergic mechanism of action and recognized that one of three patients with major depressive disorder did not adequately respond to biogenic amine antidepressants. Intranasal esketamine is the first non-biogenic amine antidepressant approved in the world.

“Virtually every biogenic amine antidepressants from Prozac to the latest were studied on the Wichita campus before they were approved,” Preskorn said.

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Matthew Macaluso, D.O., who completed his residency in psychiatry at KU School of Medicine-Wichita, is an associate professor in the school’s Department of Psychiatry & Behavioral Sciences, directs the psychiatry residency program and is assistant dean of research. Through the school’s Center for Clinical Research, of which he is the director, Macaluso conducted some of the pivotal trials that supported the approval of the new drug.

“Many of my colleagues in the psychiatry profession agree that this treatment is a game changer for the 35-40 percent of people with major depression, which is not responsive to biogenic amine antidepressants,” said Macaluso.

Biogenic amine antidepressants were the only antidepressants on the market prior to the approval of esketamine.

Wayne Drevets, M.D., is a scientist at Janssen, a pharmaceutical company of Johnson & Johnson, and leads the division that developed esketamine. Drevets also received his medical degree from KU School of Medicine in Kansas City.

The drug will appear under the brand name Spravato. The nasal spray, which acts within hours, will be administered under medical supervision and can only be used in a certified doctor’s office or clinic. Patients will then be monitored for at least two hours after receiving a dose.

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