FDA approves first prescription digital therapy for major depression

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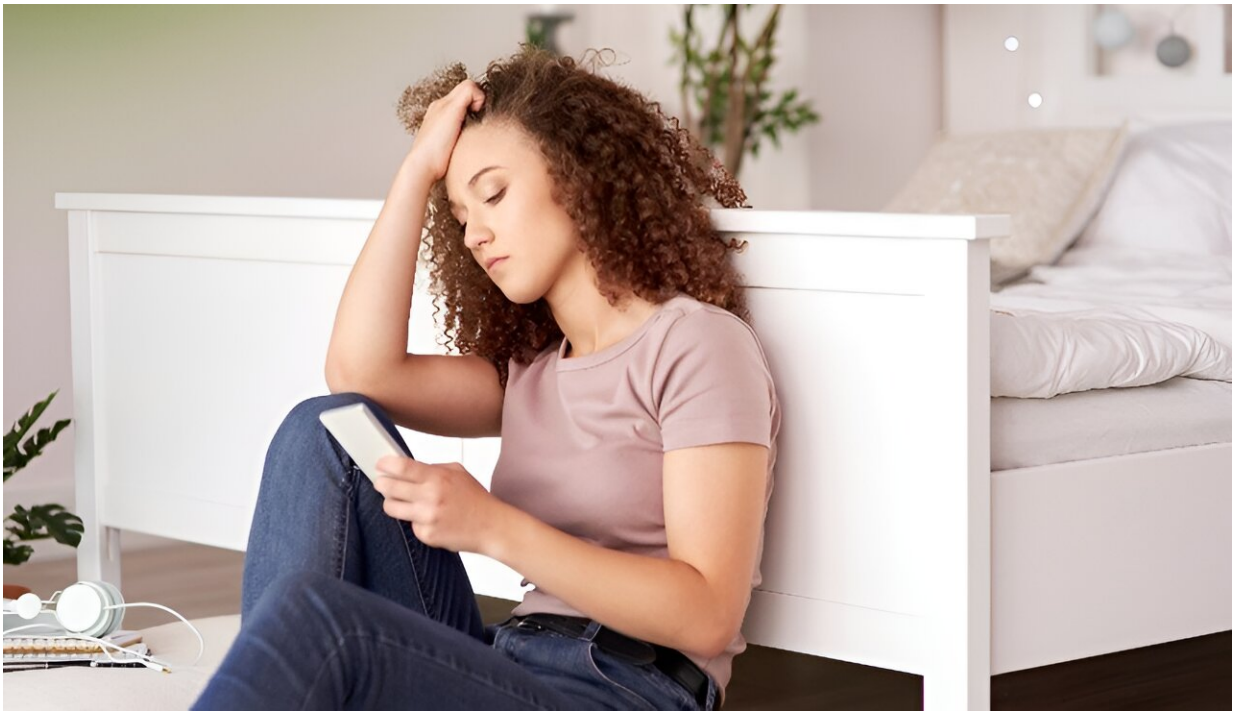

The U.S. Food and Drug Administration (FDA) has cleared the first prescription digital therapeutic authorized for the adjunctive treatment of major depressive disorder (MDD) symptoms.

The approval is for Rejoyn, a six-week treatment program that can

enhance cognitive control of emotion as an adjunct to clinician-managed outpatient care for adult patients with MDD (aged 22 years and older) who are on antidepressant medication.

The approval, which was granted to Otsuka and Click Therapeutics, was based on the 13-week Mirai study, which included 386 participants, aged 22 to 64 years, diagnosed with MDD and on antidepressant medication. Among participants who were randomly assigned to receive either Rejoyn or a sham control app, individuals treated with Rejoyn showed an improvement in depression symptom severity from baseline.

Symptom improvement was consistently detected across both patient and clinician-reported scales, including the Montgomery-Åsberg Depression Rating Scale, Patient Health Questionnaire nine-item depression scale, and the Clinical Global Impression-Severity scale.

Participants in the Rejoyn group showed continued improvement one month after completing the six-week treatment program. No treatment-related adverse events were seen.

"Rejoyn has a neuromodulatory mechanism designed to act like physical therapy for the brain by delivering personalized, consistent brain-training exercises designed to help improve connections in the brain regions affected by depression," Brian Iacoviello, Ph.D., scientific advisor at Click Therapeutics, said in a statement.

"When stronger and more balanced connections are created, the regions of the brain responsible for processing and regulating emotions are better able to work together and symptoms of depression can improve."