

**Category**

Best Digital Health Solution

**General Information****Company Name \***

Otsuka Precision Health

**Number of employees \***

51-200

**Turnover and/or Funding**

N/A

words remaining :

500

**Product/Solution Name \***

Rejoyn

**Corporate Name \***

Otsuka Precision Health, Inc.

**Date of Approval \***

2024-03-30

**Indications \***

Rejoyn is a prescription digital therapeutic for the treatment of Major Depressive Disorder (MDD) symptoms as an adjunct to clinician-managed outpatient care for adult patients with MDD aged 22 years and older who are on antidepressant medication. It is intended to reduce MDD symptoms.

words remaining :

456

**Therapeutic Areas \***

Neuroscience, Psychiatry, Cognitive Behavioral Therapy (CBT)

words remaining :

494

\*Kindly clearly label your files with company name and asset name.

**Background information and need for drug / device**

(please be as specific as possible in your description; limit 500 words)

Rejoyn is a smartphone software application (app) for the treatment of MDD symptoms. It is administered to a user via the user's smartphone device (running Apple iPhone operating system [iOS®] or Android™ operating system [OS]), which delivers a proprietary interactive cognitive emotional and behavioral therapeutic intervention.

The core components of Rejoyn are the Emotional Faces Memory Task (EFMT) exercises, brief cognitive behavioral therapy (CBT)-based lessons to learn and apply key therapeutic skills, and short message service (SMS) text messaging to reinforce CBT-based lesson content and to encourage engagement with the app.

It is designed for use as an adjunct to clinician-managed outpatient care over a period of 6 weeks for the treatment of MDD symptoms, followed by a 4-week extension period where CBT-based lesson content will be accessible but no new therapeutic content or EFMT exercises will be available.

Rejoyn is not intended to be used as a stand-alone therapy or as a substitution clinician prescribed medications.

In January 2019, Otsuka America, Inc. and Click Therapeutics, Inc., announced a historic collaboration agreement to develop and commercialize a prescription digital therapeutic for MDD. The collaboration leveraged Click's experience with digital software solutions with Otsuka's expertise in developing and commercializing approved prescription therapies for patients with serious mental illnesses. Together, the companies worked to develop Rejoyn. OPH later assumed responsibility for the commercialization of Rejoyn for MDD.

MDD affects millions of patients. It is characterized by persistent and pervasive symptoms that can significantly affect daily functions. Symptoms may include depression, feelings of sadness or hopelessness, changes in appetite, insomnia, excessive fatigue, difficulty concentrating, and thoughts of death or suicide.

Rejoyn taps into the brain's ability to change, known as neuroplasticity, to help reduce depression symptoms. For some people with depression, the feeling part of the brain and the thinking part of the brain have trouble communicating. Rejoyn works with the parts of the brain that are responsible for emotion and logic. The amygdala is the part of the brain that drives emotions such as fear, anxiety and motivation. It is a part of the limbic system which controls our fight or flight impulses and ability to sense/react to danger. The prefrontal cortex is responsible for higher cognition functions such as planning and impulse control. This part of the brain is often associated with executive functions such as problem-solving and decision-making. When these parts of the brain are not communicating properly with one another, the brain struggles to process emotions. As a result, negative emotions become more powerful, making people feel like they're spiraling.

The brain-training exercises are designed to activate these parts of the brain at the same time. This helps to strengthen the connection between them, so they're able to communicate better. This may help the brain to process emotions, improving depression symptoms. The brain-training exercises involve identifying and remembering emotions on a series of faces, which is designed to activate the amygdala. Remembering emotions is designed to activate the prefrontal cortex. Activating these simultaneously through exercises helps them work together.

words remaining :

0

\*Kindly clearly label your files with company name and asset name.

Attached Files:

- [Otsuka Precision Health Rejoyn Prix Galien Submission.docx](#)

### **History of the development of the solution/product \***

**(please be as specific as possible in your description; 500 words)**

Rejoyn was developed using a combination of innovative technology and clinical research. The Mirai trial was a pivotal, multicenter, remote, double-blinded (patients also blinded to hypothesis), randomized, controlled trial to evaluate the effectiveness and safety of Rejoyn in adult participants diagnosed with MDD who were on antidepressant therapy (ADT) for the treatment of depression (NCT04770285). The primary objective of Mirai was to evaluate the effectiveness of Rejoyn in reducing depressive symptoms compared with a Sham mobile app, which served as a control. Sham consisted of Shapes Memory Task (SMT) exercise which was matched for time and attention to the active EFMT exercise.

After they finished the 6-week treatment people using Rejoyn experienced overall reduced depression symptom severity measured by a commonly used depression severity scale in clinical trials, Montgomery-Asberg Depression Rating Scale (MADRS). On average, people reported that Rejoyn reduced their depression severity from moderately severe to mild measured by a participant-reported outcome scale of depression, Patient Health Questionnaire (PHQ-9). On average, clinicians reported that Rejoyn reduced depression severity from moderately ill to mildly ill measured by a clinician-reported outcome scale of depression, Clinical Global Impressions-Severity Scale (CGI-S). In the control arm, people using a Sham app reported reduced depression severity from moderately severe to moderate.

Rejoyn received a premarket clearance from FDA on March 30, 2024. Rejoyn claimed substantial equivalence to reSET®, a prescription digital therapeutic cleared by FDA as an adjunct to outpatient treatment of substance abuse disorder under the supervision of clinician.

words remaining :

255

\*Kindly clearly label your files with company name and asset name.

### **Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition \***

For millions of patients living with MDD, antidepressant medications and psychotherapy are effective and the standard of care. For some patients who experience a partial response to the standard treatments, healthcare providers may consider adding adjunctive medications to an antidepressant regime or increasing the frequency or duration of psychotherapy interactions. Rejoyn, which does not have medication-like side effects, provides additional adjunctive treatment options for MDD patients.

With the launch of Rejoyn, OPH also hopes to leverage the promise of technology to drive access to care, particularly in areas where there is a shortage of providers and long waitlists for appointments.

The availability of software that patients can access and use right from their smartphone with healthcare provider supervision offers the potential to address the unmet needs of certain patients in terms of access to care. OPH hopes that Rejoyn will pave the way for the adoption and use of other technologies that leverage the public's comfort with technology and its growing role in care and treatment.

words remaining :

334

\*Kindly clearly label your files with company name and asset name.

**Please provide appropriate references (PubMed, Abstract, Website) \***

Website: <https://www.rejoyn.com/meet-rejoyn>

\*Kindly clearly label your files with company name and asset name.