Developing MDMA into a Prescription Medicine for PTSD

Every year in the U.S., 8 million people suffer from PTSD, and about 300 million people worldwide. With about 27% of suicides in the U.S. associated with PTSD, and 20 veterans committing suicide every day, there is an urgent need for more effective treatments.

MAPS has raised $26.2 million of the $26.7 million needed for its FDA Phase 3 trials of MDMA-assisted psychotherapy for PTSD. MAPS is currently seeking an additional $5 million for European Medicines Agency (EMA) trials.

In MAPS’ completed Phase 2 trials with 107 participants, among 100 participants who received therapy with active dose MDMA, 56% no longer qualified for PTSD two months following treatment. At the 12-month follow-up, 68% no longer had PTSD. All participants had chronic, treatment-resistant PTSD, and suffered from PTSD for an average of 17.8 years. Most subjects received just 2–3 sessions of MDMA-assisted psychotherapy.

On July 28, 2017, MAPS concluded its Special Protocol Assessment process with the FDA, clearing the way for Phase 3 trials and confirming that if the results are successful, the FDA will approve the treatment. On August 15, 2017, the FDA granted Breakthrough Therapy Designation to MDMA-assisted psychotherapy for PTSD, acknowledging that it “may demonstrate substantial improvement over existing therapies” and agreeing to expedite its development and review.

On April 6, 2018, MPBC and MAPS Europe completed a Scientific Advice submission to the European Medicines Agency (EMA) as part of the process of obtaining approval for MDMA-assisted psychotherapy for PTSD in Europe.

Phase 3临床试验设计

- 屏幕和注册
- 3准备课程
- 8小时的心理治疗课程
- 与MDMA或安慰剂和9个整合的心理治疗课程
- 2个月的随访

Phase 3临床试验地点

Phase 3临床试验将从2018年夏季开始，预计将在美国、加拿大和以色列的16个地点招募200-300名参与者。如果Phase 3试验证明具有显著的疗效和可接受的安全性，FDA批准预计将在2021年。