MDMA-Assisted Psychotherapy for the Treatment of PTSD in Europe

MAPS and MAPS Europe have completed key negotiations with the European Medicines Agency (EMA) to conduct an international multi-site Phase 3 clinical trial of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) in the Netherlands, Germany, Portugal, Norway, the United Kingdom, Finland, and the Czech Republic.

PTSD is a serious disorder that negatively impacts a person's daily life, creates high-cost healthcare utilization, increased depression, and suicide risk. First line treatments of trauma-focused psychological therapies are either not effective or intolerable in up to half of patients. MAPS Europe aims to obtain approval for the prescription use of MDMA as an adjunct to psychotherapy in patients with PTSD.

Currently, MAPS seeks $9 million for EMA-regulated trials to supplement the data being gathered for the U.S. Food and Drug Administration (FDA). $897,735 is already raised and roughly $8.1 million is still needed.

In 2019, up to 40 participants will be enrolled in the Phase 2 open-label, two-dose lead-in study, the first multisite study of MDMA-assisted psychotherapy for PTSD in Europe. A brain imaging sub-study will explore possible biological correlates of treatment outcomes. The Phase 2 study will provide therapist supervision leading into the Phase 3 study at the same eight sites across seven European countries.

Enrollment will begin in 2020 for the Phase 3, randomized, double-blind, placebo-controlled study, which will enroll approximately 70 participants. The study will follow the same study design as Phase 3 studies currently underway in the United States, Canada, and Israel.

EU Phase 3 Study Design

Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD will enroll 70 participants across 8 sites in 7 countries in Europe.

60 Therapy Training participants from 14 countries gathered in Landgraaf, Netherlands from September 26 – October 3, 2018, to attend Part B of the MDMA Therapy Training Program, learning about "inner healing intelligence" and how the concept translates internationally.