Developing MDMA into a Prescription Medicine by 2021

Timeline for Regulatory Approval of MDMA-Assisted Psychotherapy for PTSD

Initial Phase 2 studies completed and published (U.S. and Switzerland) 2004–2010

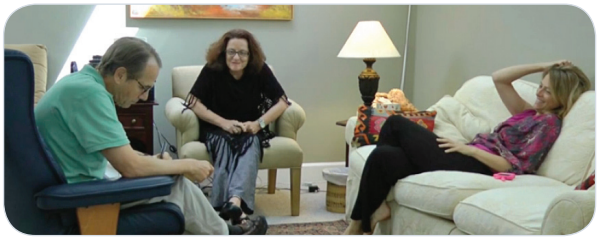
Results from MAPS' initial Phase 2 studies in the U.S. (23 treated) and Switzerland (14 treated) are published in the *Journal of Psychopharmacology* (Mithoefer et al. 2011, Mithoefer et al. 2013, Oehen et al. 2013, and Chabrol 2013). Data will be included in the End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in 2016.

Additional Phase 2 Studies (U.S., Canada, and Israel) 2010–2016

By the end of Phase 2, MAPS will have treated 103 subjects. All Primary end point data will be complete in December 2015 and all treatments will be complete the first quarter of 2016 with the remaining participants in long-term follow-up. Studies are taking place in the U.S. (26 subjects in South Carolina and 28 in Colorado), Israel (9 subjects), and Canada (6 subjects).

End of Phase 2 Meeting with FDA and Review of Phase 3 Protocol 2016

At the End of Phase 2 meeting with the FDA (Spring 2016), MAPS will present all the data from our Phase 2 studies. This meeting is an opportunity to plan the Phase 3 protocol and identify additional information that may be required to support our New Drug Application (NDA).



Michael and Annie Mithoefer with participant Rachel Hope (right).

Request for FDA Special Program 2016

With impressive preliminary Phase 2 results, MAPS plans to request an FDA special program designation. This designation is granted by FDA for research into treatments of serious conditions for unmet medical needs. If granted, MAPS will receive increased communication with the FDA throughout the Phase 3 process. MAPS will also request a Special Protocol Assessment (SPA), allowing the FDA to provide additional input into the design of our Phase 3 clinical trial protocols. This will assist us in reaching an agreement with the FDA on the scientific and regulatory requirements for the research prior to initiation.

Manufacture MDMA Under Current Good Manufacturing Practices (cGMP) 2015–2016

MAPS Public Benefit Corporation contracted with UK pharmaceutical manufacturer Shasun for one kilogram of MDMA certified under cGMP to supply Phase 3 trials of MDMA-assisted psychotherapy for PTSD.

Phase 3 Clinical Trials (North America and International) 2017–2021

Two Phase 3 trials are planned to start in 2017 (North America, 200 subjects) and 2018 (North America/International, 200 subjects). In preparation for selecting Phase 3 researchers, MAPS has developed a multi-part Therapist Training Program to teach our manualized form of psychotherapy (maps.org/treatment manual). Training began in 2015 and will focus on Phase 3 therapists through 2017, then will continue through Phase 3 to prepare for post-approval licensure.

From October 4–11, 2015, MAPS hosted a seven-day training in Charleston, South Carolina, for therapeutic professionals interested in working on MAPS' future clinical trials of MDMA-assisted psychotherapy for PTSD.

Submit New Drug Applications to Regulatory Agencies (U.S. and Europe) 2021

Phase 3 data will be submitted on an ongoing basis in order to expedite FDA review. Ongoing meetings with the FDA are expected as part of the Investigational New Drug (IND) process.

For more information, see **maps.org/mdma**.

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