We have completed telephone screening on 87 potential subjects. One potential new subject is scheduled for formal screening and two are considering it. We have added newspaper advertising to our recruitment efforts. As required, the text of the newspaper ad was approved by the IRB. We don’t know yet how many new subjects we will enroll as a result of this advertising, which is quite limited because of cost. There are other local, non-MAPS PTSD research studies taking place at the medical school and at private, for-profit, research companies. To some extent, we are competing with their much larger advertising budgets. While I’m sure this competition for subjects has slowed down our recruiting, I’m confident that we will be able to find the additional nine subjects we need.

The study is moving along smoothly and our results continue to be very promising. As we ponder the initial data we have decided to ask the FDA and the IRB for permission to make two protocol changes: 1) To add a supplemental dose of 50 mg of MDMA (placebo) two to three and a half hours after the initial dose of 125 mg; 2) To add a third MDMA-assisted psychotherapy session.

It is our impression that several subjects might have benefited from a supplemental dose of MDMA, and that several might have benefited from a third MDMA-assisted therapy session. Because this is a small pilot study, we don’t expect to prove a statistical difference between doses or number of sessions, but we think these changes could yield useful information to guide future study design.

Because ours was the first Phase II study we were very conservative in only asking for two MDMA-assisted therapy sessions and only a single dose of 125 mg of MDMA for each session. Since our initial protocol was approved, the FDA and relevant IRBs have approved an MDMA study at Harvard that will use a supplemental dose. The MAPS-sponsored MDMA/PTSD studies in Israel and Switzerland will use supplemental doses as well; the latter will also have three MDMA-assisted sessions.

It’s gratifying to note that since my last Bulletin update the MDMA studies I refer to above have all received government approval or are on the verge of doing so. Thanks to MAPS coordination, I have had the opportunity to meet with all those researchers, as well as other psychedelic researchers from the US and Europe, on a number of occasions. The Harvard and Swiss teams have both come to Charleston to visit us and become familiar with the protocol that we are using to conduct our study. My wife and co-therapist, Anne, and I are also looking forward to a visit from the Israeli team very soon. We greatly value this collaboration with other researchers so geographically separated, but so closely connected in our shared desire to explore the therapeutic potential of MDMA-assisted therapy.

After the 1993 withdrawal of the license of five members of the Swiss Medical Association for Psycholytic Therapy (SAePT), who practiced MDMA- and LSD-assisted psychotherapy for 5 years with few restrictions, we had to accept that future applications for licenses would be limited to the context of scientific research. In 2003, the Ethics Committee rejected a protocol developed by SAePT members to investigate the efficacy of psilocybin-assisted psychotherapy in recurrent depression.

In April 2005, my wife Verena Widmer and I visited MAPS President Rick Doblin, Ph.D., and MAPS-funded researchers John Halpern, M.D., and Michael Mithoefer, M.D., to discuss strategies to resume research into the therapeutic application of psychedelics in Switzerland. This meeting soon resulted in close cooperation between MAPS and SAePT, and in a short time we were able to adapt the MAPS standard protocol for MDMA/PTSD research to our study.

The proposed pilot study will investigate the safety and efficacy of MDMA-assisted psychotherapy in 12 patients with treatment-resistant post-traumatic stress disorder (PTSD), as in the ongoing MAPS-sponsored study led by Mithoefer. Based on the preliminary results from Mithoefer’s study, we modified the design to include three experimental MDMA sessions with 12.5 mg MDMA, followed by a supplemental dose of 62.5 mg after 2.5 hours. We also adjusted MAPS’ protocol to use a single placebo consisting of 2.5 mg MDMA, followed by a supplemental dose of 12.5 mg MDMA.

As in the U.S. study, patients who receive the placebo can choose to participate in a second stage of the study, in which they go through the whole process again with a full dose of MDMA. Outcome measures will be the CAPS (Clinician Administered PTSD Scale) and the PDS (Post-traumatic Stress Diagnostic Scale), a self-report scale. Due to new findings and the absence of neurocognitive deterioration in MAPS’ U.S. study, we consider these neurocognitive measures sufficient.

The protocol was submitted to the Ethics Committee in October 2005 and was approved on December 23, 2005. The application is now being reviewed by SuisseMed (the Swiss Drug Institute). Prior to the LSD conference in Basel, Switzerland, the first pre-study data monitoring visit took place at my psychiatric practice near Solothurn, Switzerland, where the study will be performed. During this meeting, we set up study procedures and Case Report Form protocol. At the time of this writing, another data monitoring visit is planned for early March. The last step will be to apply for a license from the BAG (Swiss Health Agency). We plan to begin recruiting subjects within a few months.

So far, the development of this study has proceeded rapidly, without major obstacles, thanks to substantial support of MAPS. Both MAPS and SAePT have pledged substantial contributions together 2/3 of the $150,000 study budget - but further efforts will now be to undertake the fund the study through donations. The LSD conference in Basel in honor of Albert Hofmann has helped to bring the subject of psychedelic drugs to a wider public audience and into the consciousness of the medical community. We hope that our research can be a contribution to helping psychedelic drugs get back to where they belong: in healing!

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