

## MDMA/PTSD Psychotherapy Study in Switzerland Launched

sufficient, and more reasonable, to ask subjects to refrain from speaking to the media only while their own active participation in the study is in process, rather than having to wait until the entire study is completed. This will be especially true if we extend the study by adding long-term follow-up.

The study's Data Safety Monitoring Board (DSMB) will have its final meeting in December or early January, after the 15th subject has completed the final follow-up outcome measure, which takes place two months after the final experimental session. The function of the DSMB is to review partial data at various points of completion and to determine whether the study should continue as designed, continue in a modified fashion, or be halted due to safety concerns. The DSMB has already met four times—after two subjects had been enrolled into the study, after five subjects had been enrolled, and also following completion of the study by the 5th and 10th subjects. These previous reviews found no safety concerns and recommended that the study continue to recruit subjects.

It's gratifying that, two and a half years after enrolling our first subject, we are nearing completion of this pilot protocol and are beginning to plan for the possibility of moving into FDA Phase 3 trials. It's also exciting that parallel MAPS-sponsored Phase 2 studies investigating MDMA-assisted psychotherapy for PTSD are moving forward on two other continents, in Switzerland and Israel. •

• IN SEPTEMBER 2006, the Ethics Committee (Swiss IRB equivalent) approved an amendment to my previously approved MAPS-sponsored MDMA/PTSD protocol to allow for monitoring of EEG/ERP (electroencephalographic/evoked response potential) measures in collaboration with Franz Vollenweider, M.D., at the Psychiatric University Hospital of Zürich. These additional measures were described in detail in the previous MAPS Bulletin.

• So far four potential subjects have completed telephone screening, and the first patient has passed all screening procedures and is now enrolled. This subject had the first MDMA-assisted session on Oct. 19. Both doses of MDMA were well-tolerated with no adverse effects, and no significant elevations of blood pressure. The psychotherapeutic process received a strong thrust forward during this initial session. The second session is already scheduled. This first session was also a test of the study procedures, and on the whole everything worked out as planned, with no unexpected difficulties.

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• We are recruiting patients for the study by sending letters to therapists and institutions engaged in psychotraumatology. Later, we will reach out to all psychiatric institutions and psychiatrists in private practice throughout Switzerland. Recruiting subjects for the study could be challenging because the rate of PTSD is lower in Switzerland than in other countries. Switzerland has not been engaged in any wars for a long time, and has not been affected by terrorism on a large scale. Most of the patients we see suffering from PTSD were traumatized by sexual assault, accidents or crime-related violence. On the other hand, Switzerland is home to many refugees from countries with recent armed conflicts, such as the Balkan states, or countries where torture is still common. The incidence of PTSD in these populations is much higher. However, linguistic and cultural barriers make psychotherapeutic treatment difficult, and oftentimes these potential subjects are unfortunately not eligible for our study.

• Nevertheless, we are optimistic that we will find enough subjects to complete the study. Now that it has full government approval and has been initiated, it is receiving increasing public attention. We are also receiving a growing number of inquiries by e-mail from people asking for MDMA-assisted psychotherapy or wanting to participate as volunteers in a research program. As this study continues to draw interest, I hope it will educate others about the unique therapeutic potential of MDMA and psychedelics. •



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