

Status of Clinical Trial of the Eros Therapy

UroMetrics, Inc. has four active clinical trials of the Eros Therapy for FSAD.

- **Dr. Maryann Schroder and Dr. Eric Beiber** at the University of Chicago are conducting a test of efficacy of the Eros Therapy in women who are **postmenopausal** and have arousal and/or orgasmic disorders. This trial will enroll 25 postmenopausal women not on hormone replacement therapy and follow their response to regular, 4 times per week, use of the Eros. The study has 23 patients enrolled and should be full in the next week or two. The study runs for 12 weeks so formal analysis of the data will begin in late November 2001. Maryann is preparing an abstract to present at the FSFF in October 2001 and to publish a full report in the 1st quarter of 2002 possibly in OB GYN. We also plan to present the data at ACOG 2002 in LA. Dr. Schroder's early reports are positive.
- **Dr. Maryann Schroder and Dr. AJ Mundt** at the University of Chicago are conducting a test of the efficacy of the Eros Therapy in survivors of **cervical cancer** who have been treated with broad beam pelvic radiation. Essentially all of these women have loss of lubrication, sensation and ability to orgasm. They also have significant tissue damage and the cervix and vagina may have continued bleeding and are friable, (easily torn). This study is also 12 weeks long and the intention is to enroll 30 patients. Thirteen patients are enrolled and patient recruitment has improved after an extended lull in the spring. All the first six patients have done very well and we will stop enrollment at 15 patients. With 100% response so far, statistical significance won't be a problem. Maryann is preparing a manuscript for submission to the FSFF in October 2001. Because of the dramatic results in these greatly impaired patients, we are making this our priority for a podium presentation. We also plan to publish a full report in the 1st quarter of 2002 in the New England Journal of Medicine. The NEJM will not accept the manuscript if any of the data was in a press release, unless the press release was associated with a presentation at a scientific conference. Neither UroMetrics nor the U of Chicago can make a press release not related to presentation at a scientific conference. We also plan to present the data at ACOG 2002 in LA, the Society of Gynecologists Oncologists in March 2002 and the American Society of Therapeutic Radiation

- **Dr. Irwin Goldstein**, Boston and **Dr. Kevin Billups**, St. Paul, are conducting a trial of the Eros Therapy in diabetic women with symptoms of FSAD and decreased ability to orgasm. Recruitment for this study has been difficult and we have stopped enrolling patients with 22 enrolled. Initial results are positive and I believe we will have statistically significant results even with this smaller sample. We intend to present an abstract of this trial at the FSFF and the full manuscript at ACOG 2002.
- **Dr. Dirk De Ridder** in Belgium is conducting a trial of the Eros Therapy in women with Multiple Sclerosis (MS) and symptoms of FSAD and decreased ability orgasm. This 12-week study is scheduled to enroll 20 patients and has nine enrolled so far. Enrollment has been very slow in part because of the low incidence of MS and in part because of cultural mores in Belgium. We may present this data as an abstract at the FSFF in Boston. Initial results are encouraging.
- **Dr Goldstein** is conducting a blood flow study at the BU and we plan to present this at the FSFF.
- **Dr J Berman** has conducted a blood flow study at UCLA and has submitted an abstract to the FSFF.
- **Dr. Deborah Lightner** is enrolling patients in the feasibility study. We should have 5 patients by the end of next week (August 17th). We are preparing to follow up on a successful feasibility study ASAP.