# AN OPEN-LABEL PILOT PROSPECTIVE VULVOSCOPY WITH PHOTOGRAPHY STUDY OF THE VISIBLE CHANGES IN THE VULVA, VESTIBULE AND VAGINA PRE- AND POST- TWENTY WEEKS OF DAILY ADMINISTRATION OF 60 MG OSPEMIFENE IN POST-MENOPAUSAL WOMEN WITH DYSPAREUNIA FROM VULVAR VAGINAL ATROPHY

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Each subject's baseline and end of the study vulvoscopic photographs were subsequently assessed using a four-point rating scale, the vulvoscopic genital tissue appearance (VGTA) scale. The VGTA scale has not been validated. This scale assesses ten different parameters of the appearance of the genital tissue including loss of labia majora, loss of labia minora, decreased size of glans clitoris, prominence of urethral meatus, stenosis of introitus, vestibular pallor, vestibular erythema, loss of vestibular moisture, loss of vaginal rugae, and loss of prominence of the anterior vaginal wall (Table 2). Each subject could score between 0 and 30 total points on the VGTA at each visit. A higher score of the VGTA scale was considered consistent with a worse vulvoscopic genital tissue appearance.

Baseline physical examination was performed as part of the screening. The physical exam included performance of a cotton-tipped swab testing where the examiner applied gentle pressure at each location of the vestibule: 1:00, 3:00, 5:00, 6:00, 7:00, 9:00, and 11:00 o'clock. The subject was asked to rate her pain on a scale from 0 to 3. Aggregate pain scores at baseline and study end were compared using the Wilcoxon signed-rank test.

Baseline sexual function diary data concerning dryness and sexual pain were collected. The questions of the sexual function diary have not been validated. For 4 weeks prior to each study visit, subjects recorded yes or no answers to the following questions for each sexual encounter: 1) did the subject experience dryness before and were you now less dry, 2) did the subject use lubricant during this sexual activity, 3) did the subject experience pain/discomfort during foreplay? 4) did the subject experience pain during masturbation, 5) did the subject experience pain during oral sex, 6) did the subject experience pain during intercourse, and 7) did the subject stop early because of discomfort. Diaries were collected and new ones administered at each subsequent visit. The number of total sexual events, as well as percentage of total sexual events with pain or lubrication difficulty was compared for diaries collected at week 0 and week 20 using the Wilcoxon signed-rank test.

At the completion of the study, the photographs were sorted by subject number and date of exam and assessed by the principal investigator, a sexual medicine physician, who had not examined any of the women in person. He assigned scores to the photographs using pre-determined Likert scales for the 10 parameters of VGTA scale (Table 2). Differences in pre-and post-treatment scores were compared using Wilcoxon signed-rank test for non-parametric matched pairs. All tests of significance were 2-tailed with $p<0.05$ considered significant. All analyses were performed in Stata®, version 13.