receipt of drugs, supplies, equipment or other in-kind support; GSK: Other Research Support includes receipt of drugs, supplies, equipment or other in-kind support; Lilly: Other Research Support includes receipt of drugs, supplies, equipment or other in-kind support; Pacira: Other Research Support includes receipt of drugs, supplies, equipment or other in-kind support; Pfizer: Other Research Support includes receipt of drugs, supplies, equipment or other in-kind support. The other author did not report any potential conflicts of interest.

MENOPAUSE

Effects of TX-001HR in Women With Menopause [19J]

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INTRODUCTION: In the REPLENISH trial, women with ≥50 moderate to severe hot flushes (HF)/week (VMS substudy [efficacy population; consistent with FDA guidance]) treated with TX-001HR (17β-estradiol [E2]/progesterone [P4]) had significant improvements in HF frequency and severity compared with placebo at weeks 4 and 12. This post hoc analysis evaluated HFs with TX-001HR in women with <50 moderate to severe HF/week.

METHODS: REPLENISH (NCT01942668) was a phase 3, randomized-controlled trial of postmenopausal women (40–65 years; intact uterus). Women not in the VMS substudy (with <50 moderate to severe HF/week) were randomized 1:1:1:1 to daily E2/P4 (mg/mg) of 1/100 (n=275), 0.5/100 (n=273), 0.5/50 (n=274), 0.25/50 (n=269). Changes and percent changes from baseline in frequency and severity of HF at weeks 4 and 12 were determined.

RESULTS: The mean number was 24.4–27.6 HF/week and mean severity score was 2.28–2.36 (ie, moderate to severe) at baseline. Women treated with E2/P4 doses had improvements from baseline in frequency of 11.8–16.2 HFs at week 4 and 16.6–19.5 HFs at week 12, corresponding to percent changes of 48%–66% and 67%–80%, respectively. Improvements from baseline in severity were 0.64–0.88 points at week 4 and 0.97–1.37 points at week 12, corresponding to percent changes of 28%–38% and 43%–60%, respectively.

CONCLUSION: The magnitude of improvements in frequency and severity observed with TX-001HR in women with <50 HF/week was similar to the significant improvements observed in women with ≥50 HF/week for frequency (67%–75%) and severity (30%–44%) at week 12. The benefits of TX-001HR may extend to women who have less frequent HF.

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GYNECOLOGY

Sustained Improvements in Anemia and Fatigue of AUB after a Single Course of Ferumoxytol: 6-Month Follow-up [20J]

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INTRODUCTION: Iron deficiency anemia (IDA) associated with abnormal uterine bleeding (AUB) negatively impacts patients' health-related quality of life (HRQOL). A Phase 3 double-blind, placebo-controlled trial (NCT01114139) previously found that patients unsuccessfully treated with oral iron had very poor baseline HRQOL scores associated with fatigue, and that IV iron treatment resulted in significant, clinically meaningful improvement. This subgroup analysis reports the impact of a single course of IV iron in women with AUB during the following 6-month extension study (NCT01114217).

METHODS: Patients with persistent or recurrent IDA (Hgb <11.0 g/dL and TSAT <20%) at any time during the extension study received ferumoxytol (2x510 mg IV, 3 to 8 days apart). Functional Assessment of Chronic Illness Therapy-Fatigue Scale (FACIT-Fatigue), and Linear Analogue Scale Assessment (LASA) -Energy, -Activities of Daily Living (ADL) and -HRQOL were administered at each monthly visit. The study was IRB-approved.

RESULTS: Most patients in the extension study did not require further doses, including 56% (119/212) of those with AUB. At Baseline of the double-blind trial (Hgb 9.0±0.9 g/dL) their FACIT-Fatigue scores were lower (23.6±11.85) than general (non-anemic) US population norms (40.1-43.6), and comparable to scores of anemic cancer patients receiving chemotherapy (23.9). By Week 5 FACIT-Fatigue increased significantly (37.4±10.84), and was sustained over 6 months (Month 7 score 40.7±11.53, Hgb 11.9±1.23). Significant improvements in all the LASA domains were also maintained.

CONCLUSION: This study found that for the majority of patients, significant improvements in fatigue and quality of life domains were achieved and sustained for 6 months following a single treatment of ferumoxytol.

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The Effect of Linzagolix on Bone Mineral Density (BMD): Safety Results From a Dose-Ranging Trial [21J]

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INTRODUCTION: Linzagolix is a new, non-peptide, GnRH receptor antagonist being developed to treat endometriosis-associated pain (EAP). The EDELWEISS trial is a Phase 2b, double-blind, randomized, placebo-controlled, multicenter, dose-ranging trial in and Europe evaluating oral once daily doses of 50, 75, 100 and 200 mg taken for 24 weeks. Subjects randomized to placebo were crossed-over to 100 mg after 12 weeks.

METHODS: IRB approval was obtained. Participants were women with surgically confirmed endometriosis and moderate to severe EAP. Women with a history of osteoporosis or other metabolic bone disease were excluded. BMD of the femoral neck, total hip and lumbar spine was assessed by DXA at baseline and after 12 and 24 weeks of treatment. Reading of DXA scans and monitoring of scan quality, including cross-calibration between sites, was centralized.

RESULTS: 327 patients were randomized and treated. Mean percent (95% CI P value) BMD changes for lumbar spine from baseline to week 24 in the 50, 75, 100 and 200 mg dose groups were 0.137% (-0.83, -1.11 P=.777), -0.798% (-1.57, -0.03 P=.042), -1.365% (-2.14, -0.59, P<.001), -2.602% (-3.56, -1.65, P<.001), respectively. BMD of femoral neck and total hip showed a similar pattern but with generally smaller changes from baseline.

CONCLUSION: Mean BMD losses at 24 weeks were <1% at doses of 50 and 75 mg and increased with increasing dose up to 2.6% for 200

mg. Long term use of 75 mg daily is not expected to require concomitant estrogen/progestin add-back therapy, while higher doses may require it.

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Transcervical Radiofrequency Ablation of Uterine Fibroids: US Experience From the SONATA Pivotal IDE Trial [22J]

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INTRODUCTION: The SONATA Pivotal IDE Trial was a prospective trial in the United States (US) and Mexico of the safety and effectiveness of transcervical radiofrequency (RF) ablation for symptomatic uterine fibroids. This is a subanalysis of the US cohort (125 patients at 21 centers).

METHODS: Transcervical RF ablation with the Sonata® System was performed on eligible patients with symptomatic fibroids. The 12-month co-primary endpoints were reduction in menstrual blood loss and freedom from surgical reintervention. Symptom severity, quality of life, satisfaction, safety and reductions in fibroid volume were also evaluated.

RESULTS: 125 patients were enrolled in the US cohort. Both co-primary endpoints were met: 65.3% of patients reported ≥50% reduction in menstrual bleeding and 99.2% of patients were free from surgical reintervention. 95% of patients reported reduced menstrual bleeding at 12 months. Significant mean improvements were realized in both symptom severity and health-related quality of life (33.8 points and 45.8 points, respectively; all P<.0001). Mean maximal fibroid volume reduction per patient was 63.8%. There were no device related adverse events. Mean length of stay was 2.5 hours and 50% of patients returned to normal activity within 1 day. Symptom improvement was noted by 97.4% of patients and 98.3% were satisfied, both at 12 months.

CONCLUSION: Results for US patients in the SONATA Pivotal IDE Trial were identical to, or exceeded, those from the binational cohort. These results support the efficacy and safety of the Sonata System as a new treatment standard for women affected by symptomatic uterine fibroids.

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INFECTIOUS DISEASES

5% Monolaurin Vaginal Gel for the Treatment of Bacterial Vaginosis: A Randomized, Placebo-Controlled Trial [23J]

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INTRODUCTION: Bacterial vaginosis (BV) is the most common cause of abnormal vaginal discharge and standard medical treatment is associated with a high recurrence rate. Monolaurin has antimicrobial effects on vaginal pathogens without affecting lactobacilli sp. We assessed the effectiveness and safety of 5% Monolaurin vaginal gel for treatment of BV.

METHODS: This multicenter, double-blinded, randomized trial compared 5% Monolaurin vaginal gel to vehicle placebo gel self-administered twice daily for three days. Healthy, non-pregnant, non-breastfeeding women ages 18 to 50 with BV diagnosed by Amsel criteria were enrolled and randomized 2 to 1 (Monolaurin to placebo). The Modified Intent To Treat (mITT) population had Nugent Scores ≥4. Clinical efficacy was defined as resolution of all four Amsel Criteria and therapeutic cure as Nugent Score ≤ 3. Solicited urogenital symptoms and adverse events were collected.

RESULTS: 109 women participated, with 73 randomized to treatment arm and 36 to placebo arm. Although lactobacilli sp. counts increased in the Monolaurin group compared to placebo (1.0x10^7 vs -5.2x10^6), there was no significant difference in achieving clinical cure (P=.42) or therapeutic cure (P=.99) with only 17% of the Monolaurin group and 25% of the placebo group achieving clinical cure, and only 3% of both groups achieving therapeutic cure (mITT population). There was no difference between groups in solicited urogenital symptoms (P=.24) and all were mild to moderate in nature. No serious adverse events were reported.

CONCLUSION: Short course 5% Monolaurin was well tolerated but no more effective than placebo in curing BV; however, longer courses should be evaluated.

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A Phase 2b, Dose-Finding Study Evaluating Oral Ibrexafungerp vs Fluconazole in Vulvovaginal Candidiasis (DOVE) [24J]

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INTRODUCTION: Ibrexafungerp (IBX, formerly SCY-078) is a novel IV/oral antifungal currently in development for the treatment of invasive and mucocutaneous fungal infections. IBX has broad activity against Candida spp., including azole-resistant strains. A phase 2b, dose-finding study was conducted to evaluate the safety and efficacy of oral IBX in subjects with moderate to severe vulvovaginal candidiasis (VVC).

METHODS: Randomized, double-blind, double-dummy study including 5 oral IBX treatment groups (750mg-QD 1 day, 300mg-BID 1 day, 450mg-BID 1 day, 150mg-BID for 3 days, and 300-BID for 3 days) and an