

SUPPLEMENTARY TABLE S3. NUMBER AND PERCENTAGE OF WOMEN WITH SERIOUS TREATMENT-EMERGENT ADVERSE EVENTS WITH OSPEMIFENE 60 MG

<i>Preferred term, n (%)</i>	<i>Placebo (n=958)</i>	<i>Ospemifene 60 mg (n=1242)</i>
Any serious TEAE	17 (1.8)	32 (2.6)
Appendicitis	0	2 (0.2)
Arthrodesis	0	1 (<0.1)
Autoimmune thyroiditis	0	1 (<0.1)
Deep vein thrombosis	0	2 (0.2)
Diverticulitis	1 (0.1)	2 (0.2)
Blepharoplasty	0	1 (<0.1)
Bone disorder	0	1 (<0.1)
Breast enlargement	0	1 (<0.1)
Breast prosthesis implantation	0	1 (<0.1)
Burns third degree	0	1 (<0.1)
Cardiac ablation	0	1 (<0.1)
Carpal tunnel decompression	0	1 (<0.1)
Cerebral hemorrhage	0	1 (<0.1)
Cerebrovascular accident	1 (0.1)	1 (<0.1)
Cholelithiasis	0	1 (<0.1)
Chronic obstructive pulmonary disease	0	1 (<0.1)
Dehydration	0	1 (<0.1)
Encephalitis herpes	0	1 (<0.1)
Endometrial hyperplasia	0	1 (<0.1)
Gastritis	1 (0.1)	1 (<0.1)
Gastrointestinal inflammation	0	1 (<0.1)
Global amnesia	0	1 (<0.1)
Hiatus hernia	0	1 (<0.1)
Hypoparathyroidism	0	1 (<0.1)
Intracranial aneurysm	1 (0.1)	1 (<0.1)
Lower limb fracture	0	1 (<0.1)
Mammoplasty	0	1 (<0.1)
Meningitis Candida	0	1 (<0.1)
Mesothelioma malignant	0	1 (<0.1)
Migraine	0	1 (<0.1)
Nausea	3 (0.3)	1 (<0.1)
Noncardiac chest pain	1 (0.1)	1 (<0.1)
Osteoarthritis	0	1 (<0.1)
Ovarian cyst	0	1 (<0.1)
Road traffic accident	0	1 (<0.1)
Skin reaction	0	1 (<0.1)
Spinal column stenosis	0	1 (<0.1)
Upper respiratory tract infection	0	1 (<0.1)
Ankle fracture	1	0
Bipolar disorder	1	0
Bladder prolapse	1	0
Breast cancer	1	0
Breast cancer <i>in situ</i>	1	0
Calculus urinary	1	0
Dizziness	2	0
Dyspnea	1	0
Lumbar spinal stenosis	1	0
Lung adenocarcinoma	1	0
Mitral valve incompetence	1	0
Palpitations	1	0
Patella fracture	1	0
Pericarditis	1	0
Peridiverticular abscess	1	0
Pleural effusion	1	0
Psychotic disorder	1	0
Pulmonary hypertension	1	0
RBC sedimentation rate increased	1	0
Seronegative arthritis	1	0
Suicide attempt	1	0
Tachycardia	1	0
Urinary tract infection	1	0

<sup>a</sup>TEAEs were those reported within 30 days of the last dose.  
RBC, red blood cells.