Supplementary Table S2. Number and Percentage of Women with Treatment-Emergent Adverse Events Leading to Discontinuation

| *Preferred term,*[a] n *(%)* | *Placebo* (n = *958*) | *Ospemifene 60 mg* (n = *1242*) |
|---|---|---|
| Any TEAE leading to discontinuation | 36 (3.8) | 95 (7.6) |
| Hot flush | 3 (0.3) | 13 (1.0) |
| Muscle spasms | 1 (0.1) | 7 (0.6) |
| Headache | 2 (0.2) | 6 (0.5) |
| Vaginal discharge | 0 | 6 (0.5) |
| Diarrhea | 3 (0.3) | 5 (0.4) |
| Nausea | 1 (0.1) | 5 (0.4) |
| Uterine polyp | 1 (0.1) | 5 (0.4) |
| Insomnia | 1 (0.1) | 4 (0.3) |
| Rash | 1 (0.1) | 4 (0.3) |
| Abdominal pain, lower | 0 | 3 (0.2) |
| Pain in extremity | 0 | 3 (0.2) |
| Pruritus | 0 | 3 (0.2) |
| Restless leg syndrome | 0 | 3 (0.2) |
| Weight increased | 0 | 3 (0.2) |
| Arthralgia | 0 | 2 (0.2) |
| Constipation | 1 (0.1) | 2 (0.2) |
| Deep vein thrombosis | 0 | 2 (0.2) |
| Drug eruption | 0 | 2 (0.2) |
| Drug hypersensitivity | 0 | 2 (0.2) |
| Hyperhidrosis | 0 | 2 (0.2) |
| Hyperlipidemia | 1 (0.1) | 2 (0.2) |
| Pruritus, generalized | 0 | 2 (0.2) |
| Syncope | 0 | 2 (0.2) |
| Abdominal pain, upper | 1 (0.1) | 1 (0.1) |
| Anxiety | 0 | 1 (0.1) |
| Cerebrovascular accident | 0 | 1 (0.1) |
| Dizziness | 1 (0.1) | 1 (0.1) |
| Dyspnea | 1 (0.1) | 1 (0.1) |
| Palpitations | 0 | 1 (0.1) |
| Dyspepsia | 1 (0.1) | 0 |

[a]Subjects with >1 TEAE that coded for the same preferred term were counted once for that preferred term.

TEAE, treatment-emergent adverse event.