Supplemental Table 3. Adverse events in soy and placebo groups.

	Related		Unrelated		Total
Grade of Adverse Event	**Treated**	**Placebo**	**Treated**	**Placebo**	
Grade 1	28	17	125	121	291
Grade 2	9	8	59	60	136
Grade 3	2	3	13	10	28
Grade 4			2	0	2
SAE			1	5	6
Total	39	28	200	196	463

Grade 1 AEs; probably or possibly related to treatment included bloating, gas, constipation, heartburn, nausea, high SGPT levels, breast pain, bilateral breast lumps, bloody nipple discharge, weight gain, anxiety, metrorrhagia and spotting, hot flashes, cystitis, erythema at an excision, joint pain, hypothyroidism, headaches.

Grade 2 AEs possibly or probably related to treatment included hot flashes, headache, diarrhea, hypothyroidism and joint pain.

Grade 3 events in subjects treated with the G-2535: hysterectomy for heavy bleeding from pre-existing uterine fibroids, decline in thyroid function. Unrelated grade 3 AEs included shortness of breath, headache, urinary incontinence, depression, musculoskeletal pain, myomectomy and post-operative bleeding with low hemoglobin counts.

Five SAEs occurred in subjects on soy treatment, all considered unlikely or not related to study drug (anemia from uterine fibroids requiring hospitalization two days after the last dose, depression in a patient with a history of bipolar disorder 47 days after the last dose, hospitalization for surgery for back pain 124 days after initiation of the study drug, and dyspnea 57 days after drug initiation).