**Table, Supplemental Digital Content 5. Serious adverse events during the treatment period (safety population)**

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| --- | --- | --- |
| **Treatment group, n** | **Serious adverse event (preferred term)** | **Relationship to study drug** |
| Placebo (N = 308) |  |  |
| 1 | Breast cancera | Unrelated |
| 1 | Cerebral infarction | Unrelated |
| Linaclotide (N = 306) |  |  |
| 1 | Bipolar disorder | Unrelated |
| 1 | Hemiparesthesia | Unrelated |
| 1 | Nephrolithiasisb | Unrelated |
| 1 | Uterine leiomyoma | Unrelated |

aPatient discontinued study prematurely because of this event;
bStudy drug was temporarily interrupted because of this event.