Clinical Study Report - Summary

Protocol Number:	SJX-653-006
Protocol Title:	A Phase 2, Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of SJX-653 in Postmenopausal Women with Moderate to Severe Vasomotor Symptoms
Phase:	2
Study Start Date:	09 Nov 2020
Study End Date:	07 Apr 2021
Sponsor:	Sojournix, Inc. 400 Totten Pond Road, Suite 110 Waltham, MA 02451 USA
Date:	30 Jun 2021

Study SJX-653-006 was terminated early.

At study termination time, 13 of 66 planned subjects had been randomized into the study to receive SJX-653 (N=7) or placebo (N=6).

Investigator-assessed drug-related TEAEs included 8 TEAEs in 2 subjects in the SJX-653 group and 2 TEAEs in 1 subject in the placebo group. All but 2 of these TEAEs were of mild to moderate severity. No serious TEAEs were reported in the study. One subject in the SJX-653 group was reported with a drug-related TEAE of postmenopausal hemorrhage at the EOS visit on Day 42. Another subject in the SJX-653 group had TEAEs of severe increased LFTs (ALT, AST) which were reported at the EOT visit on Day 28 which represented an AESI as defined in the protocol and were deemed probably related to the study drug. LFT increases normalized without intervention over the following 9 weeks. No other clinically relevant laboratory abnormalities, vital signs, or abnormal results from physical examinations, including a gynecological examination, were reported as treatment-emergent adverse events.

After consultation with the independent Data Monitoring Committee and unblinding of the AESI case by the Sponsor, the study was terminated early per Sponsor decision.