PRESS RELEASE

November 24, 2022

SNBL's Comments on Results from Clinical Phase 3 Studies of STS101, an Investigational Migraine Drug Candidate, Announced by Satsuma Pharmaceuticals, Inc., a Key Investee of SNBL

TOKYO and KAGOSHIMA, Japan, November 24, 2022 – SNBL (TSE:2395) today made an announcement as follows: Satsuma Pharmaceuticals, Inc. ("Satsuma", San Francisco, CA, U.S.A.), a licensee of SNBL's nasal delivery platform technology, as well as a key investee of SNBL, is currently developing a migraine drug in the U.S. (Development Code: STS101). Satsuma announced the results of Phase 3 clinical studies for STS101, which are the long-term safety study (Study Name: ASCEND) and the efficacy study (Study Name: SUMMIT), on September 20, 2022 and November 14, 2022, respectively. SNBL would like to comment and add supplementary explanations of these results as well as the future NDA submission.

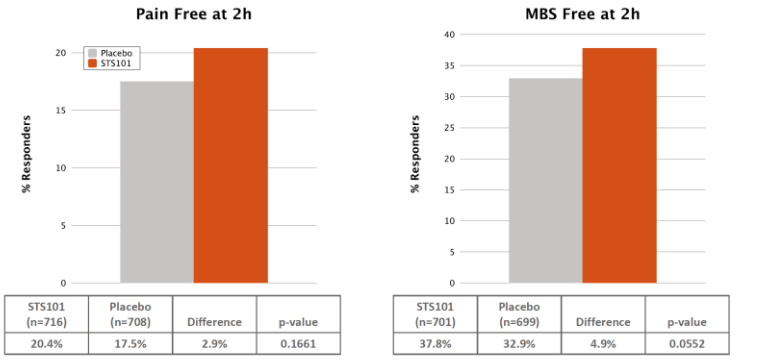
The ASCEND study, a multi-center and open-label Phase 3 study for STS101, was designed to assess the tolerability and safety of STS101_5.2 mg in the acute treatment of migraine attacks over 6 and 12 months, in more than 450 subjects. The primary endpoint was to evaluate the tolerability and safety of STS101_5.2 mg, and the secondary endpoint was to evaluate the efficacy of STS101_5.2 mg. In the ASCEND study, which incorporated an improved second-generation nasal delivery device, a total of more than 6,900 doses of STS101 were administered to more than 340 subjects. As for the results of the ASCEND study*1, although mild and transient treatment-emergent nasal adverse events of STS101_5.2 mg were reported, STS101_5.2 mg was well tolerated and safe for long-term use. In addition, favorable efficacy results from the 172 subjects such as freedom from pain (Pain Free) by 2 hours post-treatment was achieved in 34.2% of all treated attacks, and freedom from most-bothersome-symptoms (MBS Free) from among photophobia, phonophobia and nausea by 2 hours post-treatment was achieved in 53.4% of all treated attacks.

The SUMMIT study, a randomized, double-blind, placebo-controlled study for STS101, was designed to assess the efficacy of a single dose of STS101_5.2 mg (incorporated the second-generation nasal delivery device) in the acute treatment of migraine in more than 1,400 subjects. In accordance with the U.S. Food and Drug Administration's (FDA) Guidance for the Development of Drugs for the Treatment of Acute Migraine*2, the co-primary endpoints for STS101_5.2 mg, Pain Free and MBS Free at 2 hours post-dose, were statistically evaluated in comparison with placebo*3. In addition, based on the guidance, secondary endpoints including Pain Relief at 2 hours post-dose and the requirement for other migraine rescue medications at 24 and 48 hours post-dose were also statistically compared with placebo. The results of the SUMMIT study*4 are shown in Figures 1 to 3 for the two primary endpoints of Pain Free and MBS Free at 2 hours post-dose, and in Figure 4 for the secondary endpoint of Pain Relief at 2 hours post-dose. As shown in Figure 1, Pain Free and MBS Free at 2 hours post-dose for STS101_5.2 mg did not have statistically significant differences from those for placebo. One of the reasons for this result may be the high response rate in the placebo group (17.5% Pain Free

and 32.9% MBS Free). In phase 3 efficacy studies of other drugs for acute treatment of migraine (oral drugs), the response rates for placebo of Pain Free at 2 hours post-dose were reported to be 11.8 to 14.3%*5, which is relatively lower than that of the SUMMIT study. Our assumption is that STS101 may have increased the expectation of the subjects, resulting in a relatively higher response for placebo during the earlier period after administration. On the other hand, as shown in Figure 2 and 3, STS101_5.2 mg demonstrated statistically significant effect on both Pain Free and MBS Free at 3 hours post-dose and at all subsequent timepoints versus placebo. The results show that STS101_5.2 mg enables consistent and long lasting Pain Free and MBS Free. Additionally, as shown in Figure 4, the effect of STS101_5.2mg on Pain Relief, one of the secondary endpoints, was statistically significantly higher than that of placebo at 2 hours after administration, indicating that STS101_5.2mg enables relief from pain even in the early post-administration period. Furthermore, the effect of STS101_5.2 mg was statistically superior to placebo regarding the proportion of subjects requiring rescue medications to control migraine symptoms within 48 hours post-dose, showing that STS101_5.2 mg can reliably reduce migraine symptoms for a long time without additional rescue medications. Therefore, although the co-primary endpoints were not achieved in the SUMMIT study, STS101 did reliably and consistently improve migraine symptoms for a long period of time without recurrence.

In a press release dated November 14, 2022, Satsuma explained that based on their interactions to date with the FDA, the results from the STS101 Phase 1 pharmacokinetic and ASCEND studies will support the NDA filing and marketing approval for STS101.

Dr. Ryoichi Nagata, Chairman and President of SNBL, stated, "The ASCEND study demonstrated a favorable safety and tolerability profile for STS101 and the SUMMIT study demonstrated statistically significant effects on both freedom-from-pain (Pain Free) and freedom-from-most bothersome symptom (MBS Free) from 3 hours to 48 hours post-dose, versus placebo. Based on the results of these clinical studies, which have yielded a vast amount of valuable data, we are confident that STS101 will contribute to improving the quality of life of patients better than existing migraine drugs. SNBL's mission is "to support drug discovery and the advancement of medical technology to relieve human suffering. We strongly hope that STS101 will reach migraine patients as soon as possible."



STS101 (n=716)	Placebo (n=708)	Difference	p-value
20.4%	17.5%	2.9%	0.1661

STS101 (n=701)	Placebo (n=699)	Difference	p-value
37.8%	32.9%	4.9%	0.0552

1. MBS: Most-bothersome symptom from among photophobia, phonophobia or nausea declared by subject at time of treated attack
2. Subjects who took study medication, entered efficacy data at any timepoint, but did not report data at 2 hr were imputed to be treatment failures

Figure 1. SUMMIT Trial Results*2: Pain Free and MBS Free 2 hours post dose
(STS101_5.2 mg vs. Placebo)

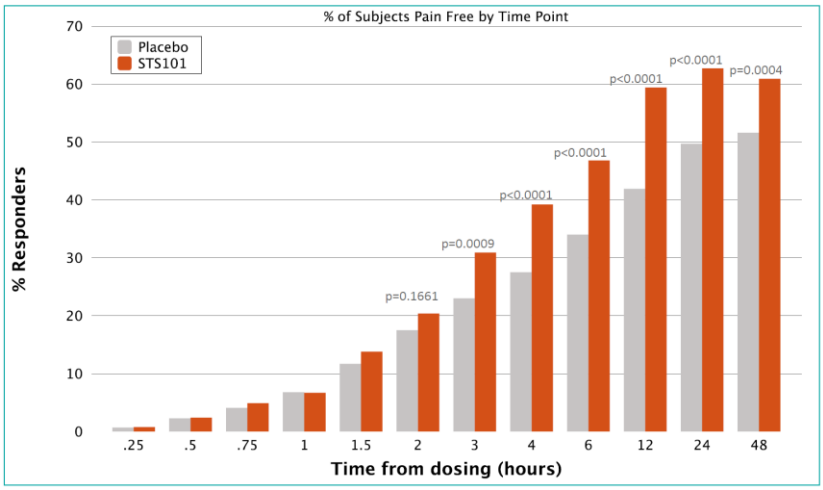


Figure 2. SUMMIT Trial Results[*2]: Pain Freedom Overtime

(STS101_5.2 mg vs. Placebo)

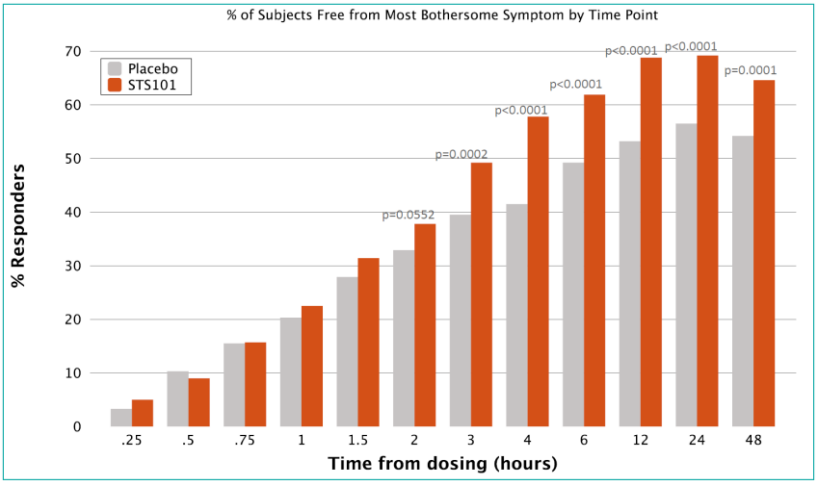


Figure 3. SUMMIT Trial Results[*2]: MBS Freedom Overtime

(STS101_5.2 mg vs. Placebo)

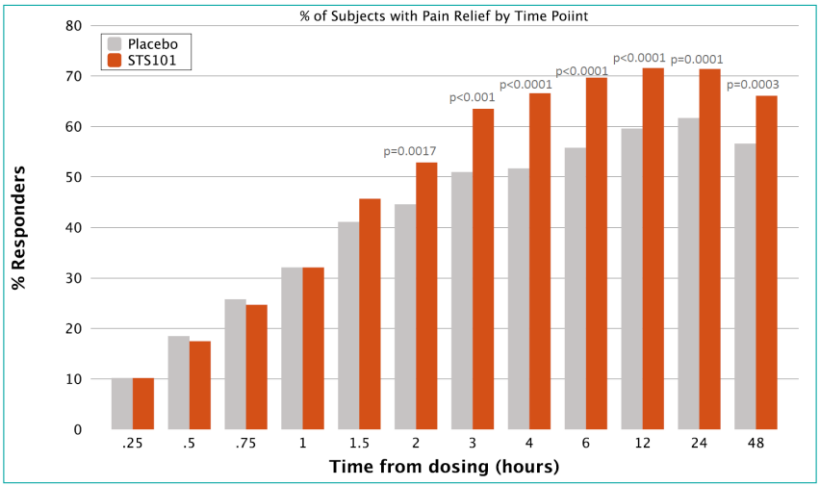


Figure 4. SUMMIT Trial Results[*2]: Pain Relief Overtime

(STS101_5.2 mg vs. Placebo)

About Satsuma Pharmaceuticals:

Satsuma Pharmaceuticals, Inc. (San Francisco, CA, U.S.A.) (NASDAQ: STSA) was established in June 2016 with the purpose of globally expanding the TR business of SNBL by developing migraine therapeutics consisting of dihydroergotamine ("DHE") and SNBL's nasal delivery platform technology, STS101.

*1: Satsuma's Press Release, Sep 20, 2022. (https://investors.satsumarx.com/2022-09-20-Satsuma-Pharmaceuticals-Announces-Positive-Results-from-the-Ongoing-STS101-ASCEND-Phase-3-Open-label,-Long-term-Safety-Trial)

*2: Migraine: Developing Drugs for Acute Treatment. Guidance for Industry. FDA, February 2018.

*3: Statistical significance is a determination about the null hypothesis, which suggests that the results are due to chance alone.

*4: Satsuma's Presentation Material for SUMMIT Phase 3 Efficacy Trial Topline Results Conference Call, Nov. 14, 2022. (https://investors.satsumarx.com/download/Satsuma+SUMMIT+results+Nov.+14%2C+2022.pdf)

*5: US clinical efficacy phase 3 results for Ubrogepant and Rimegepant for acute treatment of migraine.

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