SOM3355: Chorea movements associated with Huntington's disease

SOM Biotech

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PROFILE

SOM Biotech is a clinical-stage biopharmaceutical company focused on the accelerated discovery of therapies through a proprietary artificial intelligence-based computational technology (SOMAI PRO). SOM Biotech has an extensive portfolio of programs in orphan diseases including orphan CNS. Two programs of the company achieved positive Phase 2a results, and two were out-licensed.

SPEAKER

Dr. Maria Zimina has a Ph.D. in Biotechnology and finished an MBA program. Before joining SOM Biotech, she was working as a researcher in the area of Biotechnology and Biomedicine, and as a Business Development Project Manager at a Research Institute of Biotechnology.

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PRODUCT

SOM3355: Chorea movements associated with Huntington's disease.

MECHANISM OF ACTION

SOM3355 is a Vesicular monoamine transporter (VMAT) 2, and Vesicular Monoamine Transporter 2 inhibitor. Its specific interaction with VMAT2 and inhibition of VMAT1 provides a balanced change in monoamine signalling, ameliorating the motor symptoms of Huntington's disease but preserving mental well-being.

TARGET INDICATIONS

SOM3355 is a drug for Chorea in Huntington's disease with positive results of Clinical Phase 2a PoC. It is the only safe VMAT2(-) not related to serious adverse events like depression, suicide, parkinsonism, or neuroleptic syndrome. Being a previously developed drug for hypertension, it has a lot of safety data from previous clinical trials and pharmacovigilance studies and is considered as a NCE in the US.

The drug is eligible for Orphan Drug Designation and has the potential opportunity for an extension of indication in Tardive dyskinesia. It has the potential peak sales of $1,3B (US and EU)

Possible additional indication: Tardive dyskinesia.

CURRENT STATUS

- SOM3355 obtained positive results of the Phase 2a PoC trial in patients with Chorea in Huntington's disease in a double-blind, randomized, placebo-controlled study with 32 patients from 4 hospitals in Spain.
- The primary endpoint was an improvement in any active drug period in the Total Maximal Chorea score (TMC) of at least 2 points compared with the placebo period. The results

provided the confirmation of the expected effects of SOM3355 on the chorea symptoms related to VMAT2 inhibition.

- The drug also showed an excellent safety profile: no suicidality, no depression-induced, and no concern about QT prolongation. Currently, the company is planning the Clinical Phase 2b/3, Pre-IND with FDA is scheduled for the end of this year.

INNOVATIVE ASPECTS

- Existing VMAT-2 inhibitors increase depression and suicidality in patients with Huntington's disease, and cause parkinsonism, and neuroleptic syndrome. SOM3355 is a drug extensively developed for hypertension only available today in some Asian countries. Its excellent safety profile has been proved as by the previous clinical (more than 1300 patients) and pharmacovigilance studies, so by the clinical trial performed by SOM Biotech in Huntington's disease.
- In addition to having a better safety profile than competitors, SOM3355 is a racemic drug. One of its enantiomers can be developed as an add-on product at a higher dose improving the efficacy and safety profile.

IPR

SOM3355 has the Method of Use Patent (WO 2014/202646 A1). It was filed in 2014, and already granted in many countries (Australia, China, Russia, Japan, Singapur, Mexico, Israel and US)

PARTNERING OPPORTUNITIES

The main focus of the company is the out-licensing of the program or its co-development.