SOM Biotech presents the Phase 2b study results with SOM3355 demonstrating a unique profile with robust improvements of chorea in Huntington's Disease Patients and a safe profile with no somnolence, no akathisia and no impact on depression, suicidality or cognition.

- SOM3355 is a drug with a novel mechanism of action combining mild beta 1-adrenergic antagonism with vesicular monoamine transporter subtype 1 and 2 (VMAT1 and VMAT2 respectively) inhibition suited for the treatment of movement and psychiatric disorders
- The study showed clinically-significant improvements in chorea measured by the Total Maximal Chorea (TMC) scale in a predefined population including all subjects not taking neuroleptics as concomitant medications and with a stable baseline TMC score (defined as at least 12 and corresponding to the upper limit of the mild range), in the SOM3355 600 mg/day dose arm.
- The Clinical Global Impression of Change and Patient Global Impression of Change (CGI-C and PGI-C) showed a remarkably higher percentage of improved ("much improved" and "improved") subjects with a stronger effect in the 600 mg/day group, thus supporting the clinical significance of the chorea improvement.
- SOM3355 did not worsen patients' depression, suicidal ideation and cognitive function. No side effects of somnolence, fatigue and akathisia were associated with the treatment with up to 600mg/day of SOM3355.

Consistent treatment benefit of SOM3355 is shown on chorea when given at the dose of 600mg daily in patients without concomitant neuroleptics which are known to have a confounding role due to their effects on the dopamine pathway. Moreover, the safety profile of SOM3355 is confirmed with the absence of depression worsening, even improvement and no increased suicidality, no somnolence, no cognitive disfunction and no akathisia induced by the drug up to 600mg/day. The study results support continued development of SOM3355 for Chorea in subjects with Huntington's disease.

"The data from this study reinforce the efficacy and safety of SOM3355 observed in the previous phase 2a study, showing clinically significant improvements in Huntington chorea associated with a safety profile characterized by no worsening of depression and suicidal thoughts, no somnolence, no akathisia and no effect on cognition" said Rossella Medori, M.D., Chief Medical Officer, SOM Biotech. "These are important findings that mark the unique profile of SOM3355 among the current treatments options, given that more than a third of patients living with Huntington's disease chorea suffer from depression and up to one fifth have suicidal ideation that together with somnolence and cognitive impairment associated with present treatments may significantly disrupt daily life."

About SOM3355

SOM3355 is a drug with a novel mechanism of action characterized by mild beta 1-adrenergic antagonism and both VMAT1 and VMAT2 inhibitory activity, especially suited for chronic continuous treatment of chorea in patients with Huntington disease.

About the Phase 2b study:

A total of 140 HD patients suffering from chorea with UHDRS-TMC score ≥ 10 were randomized in 3 parallel arms: placebo, SOM3355 400mg/day and SOM3355 600mg/day.

The effect of SOM3355 on chorea was assessed using mean changes from baseline in the Unified Huntington's disease Rating Scale Total Maximal Chorea (TMC) score and chorea improvement (improved combines “minimally improved”"much improved" and "very much improved") in the CPG-I and PGI-C endpoints. In the prespecified subgroup of 122 patients without concomitant neuroleptic treatment, SOM3355 600mg daily significantly improved chorea compared to placebo, measured by a change of TMC score from baseline to end of maintenance dose (i.e. mean Week 9 and 10) of -3.46 (p= 0.04 Mixed Model analysis). From this group, the reduction in TMC score from baseline showed the greatest improvement of -4,53 at Week 9 in those patients with a stable mild baseline TMC score (defined as above 12, that is within the upper limit of mild chorea), with p=0.03 when compared to placebo at end of maintenance dose.

Remarkably, patients on SOM3355 were more than four times as likely to be rated as improved at 9 or 10 weeks according to the CGI-C and remarkably more patients rated themselves improved according tp the PGC-C compared to placebo.

Study discontinuation rates were very low with 7.2% of subjects in the high dose of 600 mg/day group. Noticeably, there were limited reports of cardiological Adverse Events, the most common being a total of 5 reports of bradycardia in the SOM3355 treatment groups. SOM3355 did not worsen depression and suicidality according to BDI (Brief Depression Inventory). Reduction in daytime sleepiness, especially at end of maintenance phase therapy for the SOM3355 treatment groups was observed. No changes in cognitive function and no akathisia were reported in all three treatment groups.

In conclusion, based on the overall results of this study, SOM3355 at the dose of 600mg/day appeared to be efficacious, safe and well-tolerated in subjects with Huntington's disease

About Chorea Associated with Huntington's Disease

Huntington's disease is a neurodegenerative autosomal dominant disorder, in which Chorea is the most prevalent sign leading to significant limitation of daily living. Chorea is an abnormal involuntary movement disorder, characterized by irregular and unpredictable movements that can affect several body parts and interfere with motor coordination, gait, swallowing and speech. The disease is progressive with continued loss of certain neurons within the brain causing cognitive and psychiatric symptoms besides the motor signs. Symptoms generally appear between the ages of 30 and 50 years and worsen over an up to 25-year period. HD is estimated to affect approximately 40,000 adults in the U.S., with more than 200,000 at risk of inheriting the disease.

About SOM Biotech: SOM Biotech (www.sombiotech.com) is a biopharmaceutical company founded in 2009 with headquarters in Spain. It uses a unique proprietary artificial intelligence (AI) platform (*SOM^{AI}PRO*) to identify new mechanism of action of small molecule drugs for the treatment of diseases with high unmet medical need with a focus on orphan disorders in the CNS space. SOM Biotech leverages on an extensive pipeline of products developed for the treatment of orphan indications among which TTR Amyloidosis, Huntington's disease and Tardive Dyskinesia, and Phenylketonuria. TTR Amyloidosis product was licensed out upon positive Phase 2a data. The SOM Board and leadership has been recently strengthened with the addition of industry veterans in the Board and highly experienced people in the management team with successful track records.

For more information about SOM Biotech, please contact:

info@sombiotech.com