SOM Biotech secures clear registrational path for SOM3355 in Huntington's disease after FDA End-of-Phase 2 Meeting

Barcelona, Spain, October 20, 2025 — SOM Biotech, a clinical-stage company dedicated to the discovery and development of innovative therapies for rare central nervous system disorders, announces today that it has received the final report on the End-of-Phase 2 Meeting held with the US Food and Drug Administration (FDA) on September 19, 2025. The Agency is aligned on the proposed Phase 3 study design followed by an open label extension (OLE) that will support the filing of a New Drug Application (NDA) for treating Huntington's disease.

SOM3355 is a drug with a unique multimodal mechanism of action that works as a selective β-blocker and a VMAT1 and VMAT2 inhibitor. It has successfully completed a Proof of Concept and a Phase 2b clinical study in Huntington's disease.

"We are excited about this positive outcome with the FDA, in addition to the recent excellent feedback from the EMA; both agencies have corroborated on the potential of SOM3355 for HD treatment," said Silvia Panigone, CEO of SOM Biotech. "We appreciate the supportive and constructive discussions with the FDA and the alignment on the proposed Phase 3 study that will drive the approval of the first drug for treating the complex symptomatology of Huntington's disease, including chorea, the behavioral and psychiatric symptoms such as depression and anxiety."

Current authorized drugs are for the treatment of chorea only, all carry a black box warning for increased risk of depression and suicidal thoughts and show side effects that cannot be distinguished from the progression of the disease.

The results from SOM Biotech's Phase 2b study in Huntington's disease showed that participants treated with SOM3355, besides exhibiting a significant improvement in chorea compared to placebo, also experienced a decrease in anxiety and an improvement in depressive symptoms, according to the Beck Depression Inventory (BDI), with a mean score reduction of -3.32 ± SD 4.845 in the SOM3355 600 mg/day treatment group that had a baseline score indicating a mild depression, with no changes in the placebo group. The study also confirmed the lack of somnolence as a side effect.

"These results showing a positive effect on depression and anxiety, with no somnolence on top of chorea improvement, are unprecedented and fulfill the unmet need for an effective and well-tolerated drug to treat HD through the different stages of the disease. The medical need for long-term tolerable treatments becomes even more relevant in cases in which disease progression is slowed down by any emerging gene therapy," said Rossella Medori, MD, CMO of SOM Biotech.

"Efficacy on behavior and psychiatric symptoms, together with a favorable safety profile, will make SOM3355 the symptomatic treatment of choice for Huntington's disease," added Panigone.

The double-blind placebo-controlled Phase 3 clinical study that will support the drug approval is expected to start in Q4, 2026 and includes the testing of one dose of SOM3355. It will enroll individuals with a diagnosis of mild-to-severe Huntington's disease.

Participants will be randomized to 600mg SOM3355 daily tablets or a placebo, for three months (12 weeks). Upon study completion, they will be eligible to enter a nine-month open-label extension (OLE) study to assess the possibility of a favorable impact on disease progression.

"We are committed to moving forward with the pivotal trial and to continuing discussions with the FDA. The alignment with the Agency on a three-month study gives us a short time period for a possible approval," concludes Medori.

About Huntington's disease (HD)
HD is a rare, hereditary, progressive neurodegenerative disorder, caused by a trinucleotide CAG-repeat expansion ≥36 in the Huntington gene. Today, there are approximately 41,000 symptomatic Americans and more than 200,000 at-risk of inheriting the disease. Huntington's disease is clinically characterized by a triad of symptoms, including motor abnormalities, neuropsychiatric disturbances and cognitive decline. At present, there is no cure for HD.

About SOM Biotech
SOM Biotech is a clinical-stage company focusing on the discovery and development of innovative therapies for patients with rare central nervous system disorders. SOM has developed a unique proprietary artificial intelligence (AI) platform (*SOM^{AI}PRO*) that has demonstrated a high clinical predictivity in identifying a drug's new mechanism of action. SOM can leverage an extensive pipeline of molecules, including products for the treatment of TTR amyloidosis (product licensed out upon positive Phase 2a data), Huntington's disease, tardive dyskinesia, phenylketonuria and Duchenne muscular dystrophy.
www.sombiotech.com

Media and analyst contact
Andrew Lloyd & Associates
Juliette Schmitt – Saffiyah Khalique
US: +1 203 724 5950
UK: +44 1273 952 481