BioSpectrum the business of Bio & Health Sciences

FDA grants Fast Track Status for SOBI003 to treat Sanfilippo A syndrome

23 January 2018 | News

Swedish Orphan Biovitrum gets Fast Track Status for SOBI003 for the Treatment of MPS IIIA and acceptance of IND application from FDA

Swedish Orphan Biovitrum AB (publ) (Sobi™) is an international specialty healthcare company dedicated to rare diseases.

The company declared that, FDA has issued a Study may proceed letter for the first study in humans, thereby accepting the investigational new drug (IND) application for the drug candidate SOBI003.

In addition, SOBI003 was granted Fast Track status by the FDA.

SOBI003 is a chemically modified human recombinant sulfamidase for the treatment of mucopolysaccharidosis type IIIA (MPS IIIA).

MPS IIIA or Sanfilippo A syndrome is a progressive, life-threatening and rare inherited metabolic disorder affecting children already from a young age.

SOBI003 was granted orphan designation by the European Commission for MPS IIIA in October 2016 and by the FDA in June 2017.

The clinical study with SOBI003 is expected to start during 2018.