

28 February 2022

Stayble Therapeutics receives approval to start Phase Ib clinical trial with STA363 for the treatment of herniated discs

Stayble Therapeutics AB ("Stayble" or the "Company") announces today that the Company has received approval to initiate the first clinical trial of its disc herniation candidate. The Company is broadening its activities by initiating a new project with STA363, targeting the indication lumbar disc herniation ("LDH"). A Phase 2b clinical trial is already underway in the indication degenerative disc disease ("DDD").

The Phase 1b study will be conducted in Poland and carried out in collaboration with the contract research company Cromsource. The primary objective of the study is to evaluate safety, and tolerability. Furthermore, disc volume, bone pain and disc intensity will also be measured as secondary endpoints. A total of 24 patients will be randomized to STA363 or placebo (2:1 distribution). After a single injection of STA363, four follow-up visits will be performed, after one week, and one, three and six months. The overall results of the study will be presented in late H1 2024.

Andreas Gerward, CEO of Stayble, comments:

"I am very proud to announce that our new indication targeting patients suffering from disc herniation is now approved by the relevant authorities to be evaluated in a Phase 1b clinical trial. We will now initiate the study and involved clinicians with the aim to treat the first patients in Q3. We are aware of the significant medical need and therapeutic gap that exists for these patients, and our ambition is to fill this need with a simple and effective single-use injection. We look forward to testing whether STA363 can offer patients an entirely new type of treatment that is both medically important and commercially valuable."

Stayble's vision is to offer patients a simple and effective treatment that addresses the underlying cause of a patient's chronic back pain, providing lasting pain relief and the opportunity for increased physical function. The company has now announced its ambition to broaden its activities and develop a treatment for patients suffering from herniated discs (LDH). Chronic herniated discs cause pain and restrict mobility in patients. Typically, patients suffering from chronic disc herniation are between 30 and 50 years old. The company estimates that 1.3 million of the 2.3 million chronic disc herniation cases in the US, EU4+UK and JP are treatable with STA363, and that 0.9 million new treatable cases are added each year.

For more information

Andreas Gerward, CEO Stayble Therapeutics AB
Mail: andreas.gerward@stayble.se
Phone: +46 730 808 397

This information is the type of information that Stayble Therapeutics AB is obliged to publish pursuant to the EU Market Abuse Regulation. The information was submitted for publication through the agency of the contact person set out above on February 28, 2023.

About Stayble Therapeutics AB

Stayble is a clinical-stage pharmaceutical company developing the STA363 injection treatment for degenerative disc disease (DDD) and chronic disc herniation (LDH). Stayble's vision is to offer patients a simple and effective treatment that addresses the underlying cause of the patient's chronic pain and provides lasting pain relief and increased physical function. Aimed at patients who are not helped by physiotherapy and painkillers, the treatment is a single injection that is expected to last a lifetime and requires minimal rehabilitation. The company is now focused on clinical development and is currently conducting a Phase 2b clinical trial in DDD and a Phase 1b trial in LDH.

Svensk Kapitalmarknadsgranskning AB is the Company's Certified Adviser.