

May 20 2020

Stayble receives approval from regulatory authorities to start clinical phase 2b study with STA363 in Russia

Stayble announces today, May 20, 2020, that the Russian regulatory authorities have approved the Company's clinical trial application on the clinical phase 2b study with STA363. The Company has previously received approval by the Russian Ethics Committee. STA363 is targeting patients suffering from chronic low back pain caused by disc degeneration.

The primary goal of the phase 2b trial is to demonstrate safety, tolerability and a clinically relevant reduction in pain in patients. The study will include about 100 patients and will be conducted at about 20 clinical sites in the Netherlands, Russia and Spain. The Company has previously received approval from Spanish regulatory authority and ethical committee. In addition, the Dutch regulatory authority has approved the Company's clinical trial application. The approval from the Dutch authority is conditioned final approval by the Ethics Committee, which has not yet finalized the review of the application.

CEO Andreas Gerward comments: The approval of our clinical trial application by the Russian authorities is an important step towards the start of our clinical phase 2b trial and a great achievement of our team and our collaboration partners. The next step after approval is site initiation, identification and recruitment of patients and treatment of the first patients. The clinical phase 2b trial is estimated to start according to plan during Q2 2020.

For more information

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

About Stayble Therapeutics AB

Stayble is a clinical stage pharmaceutical company developing the injection treatment STA363 for disc-related low back pain. The treatment is aimed at patients whose back pain persists after physiotherapy and painkillers. The injection is given once and the effect is expected to remain throughout the entirety of the patient's life and to require minimal rehabilitation. The Company's focus is set upon the continued clinical development of the upcoming clinical phase 2b study. Stayble's vision is to develop STA363 as a new standard treatment for patients suffering from chronic disc-related low back pain.

Mangold Fondkommission AB is the Company's Certified Adviser and can be reached at +46 (0)8 503 015 50 or e-mail ca@mangold.se.

The information above was provided by Stayble Therapeutics AB according to EU Market Abuse Regulations. The information was provided, through the above contact person, for publication on 20 May 2020 at 08:30 CET.