

May 1, 2020

Stayble receives approval from regulatory authorities to start clinical phase 2b study in Spain

Stayble announces today, May 1, 2020, that the Spanish 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 Spanish Ethics Committee. With both regulatory and ethical approval all prerequisites to start the trial in Spain are met. 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 Dutch regulatory authorities have previously 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. In addition, the Company is awaiting the responses from the Russian regulatory agencies.

CEO Andreas Gerward comments: The approval of our clinical trial application from the Spanish authorities are an important step towards the start of our clinical phase 2b trial and a great achievement from our team and our collaboration partners. We are now carefully following the COVID-19 development and the guidance from Folkhälsomyndigheten, WHO and European Centre for Disease Prevention and Control (ECDC) with the goal of initiating the study 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.

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