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Stayble Therapeutics Phase IIb data support effectiveness in treating herniated discs

Stayble Therapeutics AB ("Stayble" or the "Company") today presents further analyses from the Phase IIb study on degenerative disc disease (DDD) and its impact on the Company's other project on lumbar disc herniation (LDH). In patients who received the higher dose of STA363, a statistically significant difference was observed in disc intensity and disc height, which are clear signs of reduced disc volume. These effects should lead to a decrease in the volume of the herniation and, thus, pain reduction in patients with herniated discs.

In the ongoing analyses of results from the DDD study, a dose-dependent reduction in disc height and intensity was observed from the MRI scans. In the highest dose group, these changes were statistically significant compared to placebo (disc height: $p=0.0001$; intensity: $p=0.0635$). A statistically significant reduction in disc height was also observed in the lower dose group. Lowering of disc height is an indirect measure of a reduction in disc volume. Consequently, a decrease in disc height indicates that treatment with STA363 achieves the desired volume-reducing effect in the treatment of herniated discs. The intensity measured with MRI provides a measure of the water content in the disc, so a decrease in intensity is a prerequisite for the disc volume and pressure reduction.

Andreas Gerward, CEO, comments:

"Strengthened by having confirmed a change in disc intensity and volume with STA363, we look forward to results from the ongoing Phase Ib study. The higher dose of STA363 is used in the LDH study, and the choice of dose is very appropriate since it has greater effects than the lower dose. We continue to analyze Phase IIb data and will update the market as soon as these analyses are completed."

The LDH project is based on the hypothesis that STA363 reduces the disc's volume, which in turn reduces the herniation's volume and pressure on nerve roots, thereby reducing pain. A relationship between a treatment that reduces disc and herniation volume, and the ensuing effect on nerve root pain, is the foundation for the therapeutic principle we are pursuing, which has been validated in the scientific literature.^{1, 2, 3}

For more information

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¹ Splendiani et al. MR assessment of lumbar disk herniation treated with oxygen-ozone diskolysis: the role of DWI and related ADC versus intervertebral disk volumetric analysis for detecting treatment response. 2013

² Bitz et al. An evaluation of narrowing following intradiskal injection of chymopapain. 1977

³ Murphy et al. Percutaneous Treatment of Herniated Lumbar Discs with Ozone: Investigation of the Mechanisms of Action. 2016

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, has finalized a Phase 2b clinical trial in DDD, and is conducting a Phase Ib trial in LDH.

Svensk Kapitalmarknadsgranskning AB is the Company's Certified Adviser.