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Stayble Therapeutics presents the final data from the phase IIb study

Stayble Therapeutics AB ("Stayble" or the "Company") today presents the final data analysis of the Company's phase IIb study with STA363 against chronic disc-related back pain (degenerative disc disease, "DDD"). Consistent with the preliminary topline analysis communicated in a previous press release, the subgroup analyses verify previously announced results where no difference in pain between placebo and active groups could be detected. In patients who received the higher dose of STA363, a statistically significant difference in disc intensity was observed and in both active doses a statistically significant reduction in disc height was shown. These changes clearly show that STA363 affects the disc and produces a reduced disc volume.

As previously communicated, the randomized double-blind study did not achieve the primary objective. According to the predetermined statistical criteria, STA363 compared to placebo did not show a statistically significant reduction in pain after six or twelve months. STA363 showed a continued good safety profile for up to twelve months. The study's secondary efficacy measures regarding function and quality of life also showed no significant differences between the two dose groups and the placebo group. Further analyses have been carried out on different subgroups to determine any effect in these groups. Among other things, differences between countries, patient age, level of connective tissue conversion, disc height changes, etc., have been analyzed. These analyses have not shown an effect regarding pain relief compared to placebo, i.e., no specific subgroup has responded better. The previously communicated result thus stands, as does the Company's assessment that the study is conclusive.

The company will now concentrate on the phase Ib project in disc herniation (LDH) where the results from the phase IIb study strengthen the company. In patients who received the higher dose of STA363, a statistically significant difference was established in disc intensity and disc height, which are clear signs of a reduced disc volume. A connection between a treatment that reduces disc and herniated volume and the effect on disc herniated nerve root pain is the basis for the treatment principle we strive for and which has been validated in the scientific literature.^{1,2,3}

Andreas Gerward, CEO, comments:

"Despite the disappointment that the study did not produce the results we hoped for, it is very encouraging that we were able to establish effects on the disc that clearly support our hypothesis in our herniated disc project. Therefore, we are shifting the focus to our ongoing phase Ib study in disc herniation, where patient recruitment is ongoing at four clinics in Poland. At the same time, we cut down on personnel and overhead costs to give the company the necessary runway to present results from phase Ib in disc herniation without additional funding. We look forward with confidence to the next step in 2024.

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

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

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

For more information

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About Stayble Therapeutics AB

Stayble is a clinical pharmaceutical company developing the injection treatment STA363 for degenerative disc disease (DDD) and chronic disc herniation (LDH). Stayble's vision is to offer patients a simple and effective treatment that targets the underlying cause of the patient's chronic pain and provides lasting pain relief and increased physical function. The treatment is aimed at patients who are not helped by physical therapy and painkillers and is a single injection that is expected to last a lifetime and requires minimal rehabilitation. The company has recently presented final data from phase 2b within DDD that do not support continued development; hence, the focus is now on the continued clinical development within LDH, where a phase 1b study is being carried out.

The company's Certified Adviser is Svensk Kapitalmarknadsgranskning AB.