

Xbrane enters a non-binding term-sheet with STADA for collaboration on Spherotide and updates regarding further development

Xbrane Biopharma AB ("Xbrane" or the "Company") today announces that the company has entered a non-binding term-sheet with STADA Arzneimittel AG ("STADA") for cooperation regarding sales and marketing of Spherotide for Europe. Furthermore, the Company updates on its plans to take the product into a phase III study in endometriosis patients.

Non-binding term-sheet with STADA

The Company's non-binding term-sheet with STADA consists of an agreement to cooperate on Spherotide regarding development, sales and marketing for Europe. The non-binding terms of the agreement means that the parties intend to share continued development costs related to Europe and the profit from the sale of the product in Europe. The non-binding agreement also includes development-based milestones, in total amounting to a low single-digit million-euro value. If the due diligence and negotiations proceed according to plan Xbrane and STADA are expected to enter into a binding agreement during 2019^[1].

Further development of Spherotide

Xbrane develops two formulations of Spherotide, one administered once a month and one administered every third month. Xbrane plans to conduct a pivotal phase III trial with the 1-month formulation in approximately 150 endometriosis patients in China and Europe to support market authorization for endometriosis, myoma and breast cancer indications in both regions. Clinical trial application is expected to be submitted during the second half of 2019 after: 1) final binding agreement with STADA is in place; 2) completion of ongoing upgrade of the quality system at Xbrane's contract manufacturer ICI (expected to be finalized in summer 2019); and 3) conducted scientific advisory meeting with NMPA (National Medical Products Administration in China). Based on the interim data from the endometriosis trial, clinical trials in prostate cancer patients for both 1-month and 3-month formulations will follow.

[1] The non-binding term-sheet that has been signed does not constitute any guarantee for that a binding agreement will be signed.

Contacts

Martin Åmark, CEO/IR
M: +46 (0) 763-093 777
E: martin.amark@xbrane.com

Susanna Helgesen, CFO
M: +46 (0) 708-278 636
E: susanna.helgesen@xbrane.com

About Us

Xbrane is a commercial phase Swedish biopharmaceutical company specialized in biosimilars. Xbrane has a patented protein production platform for development of biosimilars and world leading expertise in biosimilars. Xbrane's headquarter is located in Solna outside of Stockholm and the company's in-house research and development facilities are in Sweden and Italy. Xbrane is listed at Nasdaq First North since February 3rd, 2016 under the name XBRANE and Avanza Bank AB is Xbrane's certified adviser (corp@avanza.se, +46 (0)8 409 421 20). For more information see www.xbrane.com.

This information is information that Xbrane Biopharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2019-06-04 08:00 CEST.

Attachments

[Xbrane enters a non-binding term-sheet with STADA for collaboration on Spherotide and updates regarding further development](#)
