

LIDDS Liproca® Depot Phase IIb study results presented at EMUC19 showing both primary and secondary endpoints being met

UPPSALA, SWEDEN – LIDDS AB (publ) Phase IIb clinical data from the LPC-004 prostate cancer study on LIDDS Liproca® Depot were presented today in an oral session at the 11th European Multidisciplinary Congress on Urological Cancers, EMUC19. The study met both its primary and secondary endpoints as well as demonstrated that a larger proportion of intermediate risk patients, which is the Liproca Depot target group, are PSA responders. The presentation can be accessed through LIDDS webpage and are also attached to this release.

The phase IIb results from the LPC-004 prostate cancer study was presented as “Late Breaking News” at EMUC in Vienna on November 16, 2019 by Professor Laurence Klotz, a world leading expert in Active Surveillance of prostate cancer patients. Professor Klotz was one of the LPC-004 study investigators and is Professor at the University of Toronto Division of Urology at the Sunnybrook Health Sciences Centre in Canada.

The preliminary data recently released from the phase IIb study, LPC-004, confirms that 90 % of patients receiving 16 ml intraprostatic injection of Liproca® Depot experienced a PSA reduction and also that 16 ml is the optimal dosage for future Phase III studies. Further, the study showed no systemic hormonal adverse reactions, that Liproca® Depot is safe and well tolerated by the patients, and that 84 % of patients being treated were amenable to a second injection of Liproca® Depot.

As LIDDS advances Liproca® Depot towards late-stage clinical development, LIDDS intends to target intermediate risk patients in its phase III trial. The LPC-004 study showed that a larger proportion of intermediate risk patients are PSA responders and that this group display a stronger mean PSA decrease compared to low risk patients.

– The results confirm that Liproca® Depot can offer a completely novel approach to complement active surveillance in intermediate risk prostate cancer patients. Liproca® Depot is well tolerated without the hormonal side effects associated with anti-androgen therapy, and is equally easy to administer as performing a prostate biopsy. Liproca® Depot treatment could contribute to the benefit of prostate cancer patients in the future, says Professor Laurence Klotz, a world leading expert and one of the study investigators and Professor at the University of Toronto Division of Urology.

– The results regarding the intermediate risk patients further validate the continued clinical development of Liproca® Depot. As announced recently, our licensing partner, Jiangxi Phuong, has decided to progress with the phase III trial in China and we will continue the commercial activities in order to sign further licensing agreements in other major markets, says Monica Wallter, CEO, LIDDS.

About the Phase IIb Liproca® Depot clinical trial

The single blind, two-part dose finding study aimed to determine the highest tolerable dose of Liproca® Depot in part I and to determine the level of PSA reduction for part II patients at month 5. The study was conducted at eight specialist urology clinics in Canada; Lithuania and Finland. The study involved 61 patients diagnosed with localized non-aggressive prostate cancer who were on Active Surveillance. Patients were followed for six months to assess response and tolerability. Three previous clinical trials (LPC-001, LPC-002 and LPC-003) involved a total of 57 patients and showed promising results for tolerability and effect on tumor tissue, prostate volume and the PSA biomarker.

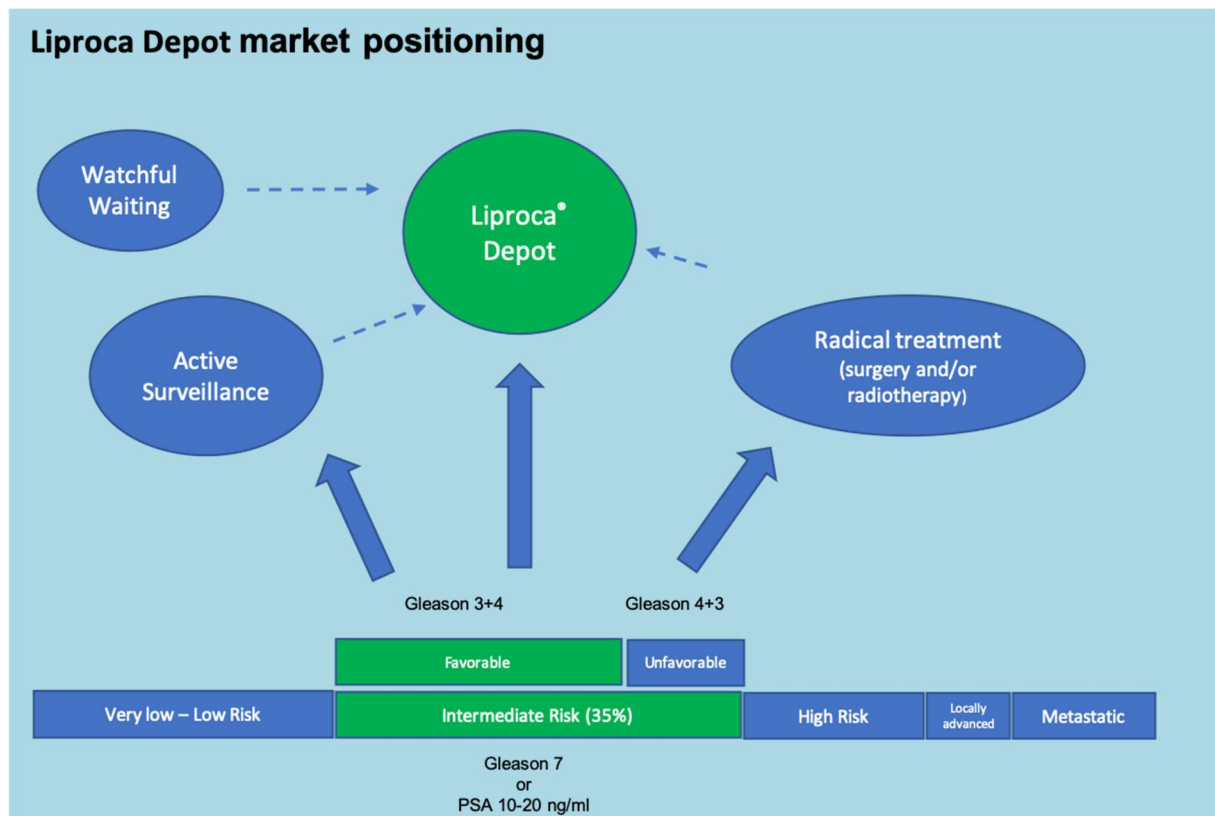
About prostate cancer and the market

Of the 1.2 million men diagnosed with prostate cancer globally each year, about 420,000 are assessed as intermediate risk and placed on ‘Active Surveillance’ where they are monitored regularly. There is no standard drug treatment for these cancer patients and many treating doctors see an unmet need.

According to market research firm GlobalData, the global market for prostate cancer drugs is expected to grow to USD 8.3 billion annually by 2023. Liproca® Depot’s target group is an untapped market potentially exceeding USD 3 billion per year.

About Liproca® Depot and NanoZolid®

NanoZolid® is a safe, flexible and functional method of delivering drugs. When injected, NanoZolid® forms a solid depot releasing the active drug over periods of potentially more than six months. As it releases its drug load, the NanoZolid® depot dissolves and is absorbed harmlessly into the body. Liproca® Depot combines NanoZolid® and 2-HOF (2-hydroxyflutamide), a well-established antiprostate cancer drug. Liproca® Depot’s target group is patients under Active Surveillance (AS) with intermediate risk of cancer progression.





For additional information, please contact:

Monica Wallter, CEO, LIDDS +46 (0)737 07 09 22 monica.wallter@liddspharma.com

This information is such that LIDDS AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact persons above, at 10:10 CET on November 16, 2019.

LIDDS AB (publ) is a Swedish-based pharmaceutical company with a unique drug delivery technology NanoZolid®. NanoZolid® is a clinically validated drug development technology and superior in its ability to provide a controlled and sustained release of active drug substances for up to six months. LIDDS has licensing agreements where NanoZolid is combined with antiandrogens and in-house development projects in clinical and preclinical phase for cytostatics and immunoactive agents. LIDDS (LIDDS) shares are listed on Nasdaq First North Growth Market. Redeye AB, certifiedadviser@redeye.se, +46 (0)8 121 576 90, is a certified adviser to LIDDS. For more information, please visit www.liddspharma.com.