

Liproca Phase IIb study results indicate cancer control

UPPSALA, SWEDEN – LIDDS AB (publ) announces that final data from the LPC-004 study confirms Liproca® Depot's potential as a safe and effective anti-androgen treatment for prostate cancer patients that currently are not treated but kept under 'Active Surveillance'. The study met both primary and secondary endpoints. MRI data shows no progression of the prostate cancer in any patients, and even regression in some patients. The final study data completes the LIDDS data room needed for external parties that are interested in licensing or acquiring Liproca® Depot.

The best efficacy was seen in the group that received 16 ml injection:

- 95% of the patients showed a decrease in PSA
- 57% of the patients were classified as responders at month
- PSA maximum response rate during the study period was 67%

The MRI analyses showed that:

- PI-RADS score was unchanged or improved for all patients
- In the second part of the study, 7 of the 41 patients showed an improvement in PI-RADS score at month 5, which indicates lower grade of cancer

After an optional biopsy, taken by 6 patients, 5 patients were stable while 1 patient showed a decrease in Gleason score (less aggressive cancer).

-The results from the final analysis confirm the benefits seen in earlier studies and from the preliminary results already presented. Our objective is to control prostate cancer with Liproca® Depot. We are pleased to see the promising biopsy and MRI results, indicating disease control and tumor regression, said Monica Waller, CEO of LIDDS.

The safety and quality of life assessment also showed positive results:

- No hormonal side effects
- All doses were well tolerated
- 90% of the patients felt that it was important or very important to receive treatment for their prostate cancer
- 80-90% of the patients considered it to be valuable to receive treatment via a local injection

-Patients are placed under Active Surveillance today to avoid the unfavorable side effect profile of the treatments currently available. Liproca® Depot is an appealing drug candidate as it has no hormonal side effects, does not alter erectile function, and is free of long-term side effects. In addition, it is easy to administer, said Laurence Klotz, a world leading expert and one of the study investigators and Professor at the University of Toronto Division of Urology at the Sunnybrook Health Sciences Centre in Canada.

Overview of study results:

Key data	16 mL dose (21 patients)	20 mL dose (20 patients)
PSA maximum response rate	67%	50%
PSA responder rates at month 5	57%	40%
Share of patients showing a PSA reduction	95%	80%
Median PSA reduction at nadir*	35%	28%
PSA nadir occurrence at week	11	18
Median change in prostate volume	-9.1%	-12.4%

*Nadir is the lowest PSA level achieved in the study and this parameter is an important determinant of outcome that separates patients with good or bad prognosis.

The study also includes an Open Label Extension (OLE) offering patients a second injection of Liproca® Depot when the PSA returns to baseline. 12 patients entered the OLE study, and at month 10 after the first injection, only 6 of patients had returned to the same PSA level as before the treatment, indicating a long-lasting effect.

About the LPC-004 study

The single blind, two-part dose finding study aimed to determine the highest tolerable dose of Liproca® Depot and to determine the level of PSA reduction for part II patients at month 5 (primary endpoints). 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. Following the LPC-004 study, a voluntary open label extension study was initiated offering patients participated in the LPC-004 study a second injection of Liproca® Depot once the patient’s PSA level (a biomarker for prostate cancer) had returned to its pre-treatment level to understand the long-term anti-androgen efficacy of Liproca® Depot. These patients are followed for up to a further year to assess safety and quality of life parameters after a repeated Liproca® Depot injection. The patients entering the OLE study are followed for 6 months and the last visit will be in July 2020.

About prostate cancer and the market

Of the 1.3 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 treatment for these cancer patients and many treating physicians see an unmet need. According to the 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 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 up to six months or more. 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 prostate cancer drug. Liproca® Depot's target group is patients under Active Surveillance (AS) with intermediate risk of cancer progression.

For additional information, please contact:

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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 on May 19, 2020 at 08:30 CET.

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.