Background: Phase IIb Liproca® Depot preliminary data

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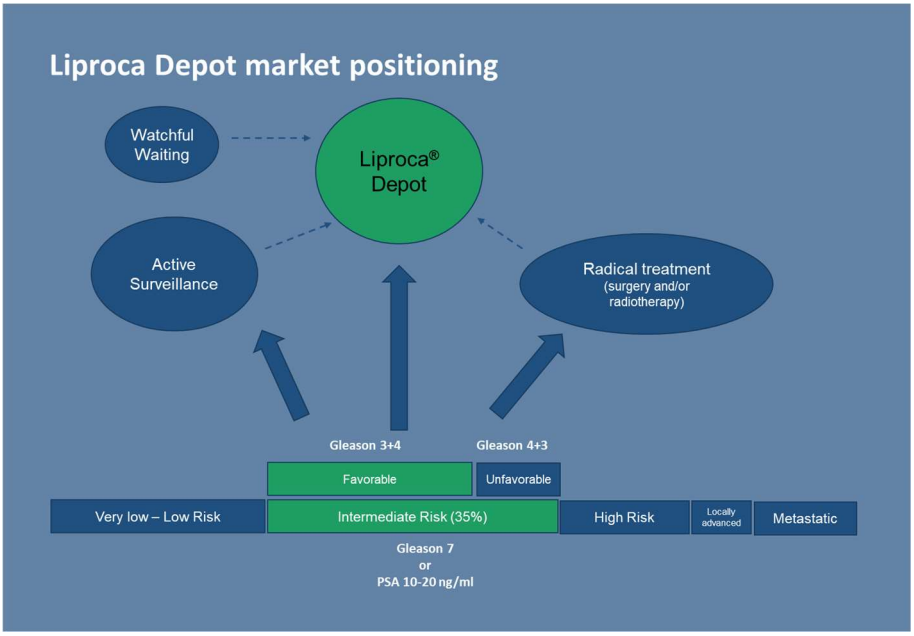
About Liproca® Depot and the drug delivery technology NanoZolid®

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 anti-prostate cancer drug. Liproca® Depot's target group is patients under Active Surveillance (AS) with intermediate risk of cancer progression.



About prostate cancer

Prostate cancer is one of the most common forms of cancer and approximately 1.2 million men around the world are diagnosed with the disease every year[1]. It is estimated that by 2030 one in five men will be affected by prostate cancer.

[1] Bray F et al, Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2018;68(6):394–424

About 420,000 (35%) of men diagnosed with prostate cancer are assessed as intermediate risk and most have a risk of disease progression[2]. These patients are usually placed on 'Active Surveillance' and are monitored for any signs of cancer progression. Anti-androgen treatments are not indicated for this patient group, due to the unfavorable side effect profile of these drugs. The most common markers used to test for is the presence and progression of prostate cancer is the level Prostate-Specific Antigen (PSA) in blood.

Most drugs currently available for the treatment of prostate cancer have severe hormonal side-effects and quality of life impacts. The global market for prostate cancer drugs is expected to grow to USD 8.3bn by 2023[3].

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.

Part I			Part II		
Cohort	Dose	No. patients	Cohort	Dose	No. patients
1	35% of prostate volume	10	3	16 ml	21
2	45% of prostate volume	10	4	20 ml	20

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. A full statistical analysis of the study data has not yet been completed.

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.

Frequently asked questions and answers

Q: Did the Phase IIb study achieve its primary objectives?

A: Yes, we have met the primary objectives and the preliminary data shows that Liproca® Depot was well tolerated and that there was a sustained PSA reduction at month 5 for patients in part II.

Q: How do these results compare to previous Phase II studies?

A: When compared to the previous phase II studies, the preliminary data for this study shows a stronger PSA effect with the higher doses in Part II, confirming an expected dose-response relationship. The Phase IIb study also shows a continued PSA reduction over a period of six months, thus validating the NanoZolid® technology.

[2] Ibid
[3] GlobalData Plc, Global prostate cancer drug forecast

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Q: What does the preliminary data show for prostate volume?
A: Despite injections of 16ml and 20ml in part II, which have an impact on prostate size, we see that the majority of patients had a reduction in prostate volume.

Q: How did results in part I vary from part II?

A: Part I of the study focused on tolerability and safety. Liproca® Depot was injected into the prostate gland at higher volumes than in previous studies.

Part II of the study focused on efficacy of the higher dose levels in the study, 16ml and 20ml. Both parts of the study confirmed the release pattern of 2-hydroxyflutamide from NanoZolid®. With the increased dose levels of Liproca® Depot, the PSA response was stronger in part II of the study.

Q: What is the relationship between PSA nadir and the Liproca Depot release over six months?

A: The peak PSA reduction (nadir) was in line with the expected pattern for NanoZolid® and Liproca® Depot's sustained release. For part II patients, nadir occurred in months 2-4 followed by a sustained PSA reduction over the 6-month period that Liproca Depot releases its drug load.

Q: What does the preliminary data show for the part II cohort that received 20ml?

A: The 20ml group in stage II shows the same pattern as for the 16ml group and the preliminary data points to the effect of 20ml being no greater than for 16ml.

Q: What is the best dosage for Liproca Depot in Phase III?

A: This dose-finding study was designed to help identify the optimal dosage for future Liproca® Depot Phase III studies. Based on the preliminary results, we can confirm that the study design and the doses studied were adequate for this purpose. The dosage for Phase III study protocols will be based on the final set of Phase IIb data.

For more information, please contact:

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