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.

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. Antiandrogen 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.

<table>
<thead>
<tr>
<th>Part I</th>
<th>Part II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort</td>
<td>Dose</td>
</tr>
<tr>
<td>1</td>
<td>35% of prostate volume</td>
</tr>
<tr>
<td>2</td>
<td>45% of prostate volume</td>
</tr>
</tbody>
</table>

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.

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.

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2 Ibid
3 GlobalData Plc, Global prostate cancer drug forecast
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.

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