

LIDDS announces positive preclinical data for NanoZolid®-TLR9 agonist project

UPPSALA, SWEDEN – LIDDS AB (publ) has performed preclinical studies using a TLR9 agonist formulated with NanoZolid® (NZ-TLR9) showing that a single NZ-TLR9 injection is reducing tumor growth and improves the survival rate. The in vivo efficacy is as good as with repeated injections of the standard TLR9 agonist. The pharmacokinetic analysis of treated tumors has confirmed the depot function of NZ-TLR9.

Clinical data have shown that intratumoral delivery of TLR9 agonists can effectively treat solid cancers. The NanoZolid® technology can provide sustained intratumoral release of the injected TLR9 agonist, minimize the need for repeated injections, and allow for a safer treatment of deep-lying tumors. LIDDS preclinical trials in a syngeneic mouse model where LIDDS NZ-TLR9 was intratumorally injected with the NanoZolid® technology shows that the antitumoral immune responses were enhanced as well as showing strong antitumoral efficacy data. Importantly, NZ-TLR9 injection is similar in antitumoral efficacy as repeated injections with a standard non-formulated TLR9 agonist.

-TLR9 is one of the most promising immunotherapy targets with a great potential both as monotherapy and in combination with other therapies such as checkpoint inhibitors. The NanoZolid® technology addresses key issues in developing TLR agonists as repeated intratumoral injections are needed using standard formulations, said Monica Wallter, CEO of LIDDS.

A preclinical programme is ongoing to further deepen the data obtained so far and LIDDS is preparing for a phase I clinical trial using NanoZolid® combined with a TLR9 agonist. The first human study is planned to start in 2021.

To increase antitumoral efficacy and avoid severe systemic side effects, TLR9 agonists are predominantly given as intratumoral injections. However, the need for repeated intratumoral injections when using standard formulated TLR9 agonists poses a risk for the patients and increases the costs for the healthcare systems. The NanoZolid® technology having a longer and controlled drug substance release is suitable for a TLR9 agonist treatment, enabling a potential reduction in number of injections and patient compliance.

-I'm really proud of the LIDDS team that successfully have developed a NanoZolid® controlled-release formulation of a TLR9 agonist. There is significant commercial potential in this area of research and drug development and the market for TLR agonists is expected to be worth hundreds of millions of dollars over the coming years, commented Monica Wallter.

About TLRs and TLR9

Toll-like receptors (TLRs) are a key target for the pharmaceutical industry in the fight against cancer. TLRs are expressed on various immune cells, including dendritic cells, and upon activation they initiate the body's immune response. TLR9 activation can lead to an immunologically active or inflamed tumor environment which then recruits the cytotoxic T cells necessary for an antitumor response in immunotherapy. Thus, TLR9 agonists can convert immunologically "cold" tumors to immunologically "hot" tumors. There are several relevant target cancers for the TLR9 project. Among these are head and neck cancer, prostate cancer and lymphomas. These cancers are diagnosed in around 2 million patients each year.



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 08:30 CET on March 25, 2020.

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.