

Neogap receives CTA approval for a phase I/IIa clinical trial with its advanced cell therapy

Neogap Therapeutics today announces that the Swedish Medical Products Agency has approved the company's application to start a clinical trial of its personalised cell therapy against colorectal cancer. The phase I/IIa trial is planned to be initiated during the first half of 2023.

Neogap's cell therapy product pTTL (personalised Tumor Trained Lymphocytes) is a unique immunotherapy that aims to treat solid tumors by training the immune system to recognize neoantigens and thereby attack the cancer. A neoantigen is an altered protein only found in the tumor after a mutation has occurred in a gene.

The study, which includes up to 16 patients with advanced colorectal cancer, will be conducted at Karolinska University Hospital in Stockholm and Västmanland Hospital in Västerås. The primary objective of the phase I/IIa trial is to determine the tolerability and safety of Neogap's therapy. The trial is conducted as a dose escalation study, starting with a low dose that is gradually increased. The expected start of the trial is H1 2023.

"The approval and the prompt initiation of the clinical trial represent significant milestones for Neogap. We have demonstrated that we can take an advanced cell therapy product from preclinical to clinical development. I am very proud of our skilled and committed team who, together with experienced partners, have brought us to this important point. As a result, we are now taking a big step towards our goal of curing cancer patients who would otherwise not survive," says Samuel Svensson, CEO of Neogap.

About the Neogap cell therapy:

The cell therapy pTTL (personalised Tumor Trained Lymphocytes) is based on Neogap's proprietary technologies PIOR[®] and EpiTCer[®]. PIOR[®] is a software utilizing algorithms and machine learning. It is applied to select the most suitable neoantigens for each patient. EpiTCer[®] is a method for proliferating the T cells that recognize the selected tumour-specific target structures to attack the cancer while leaving healthy tissue untouched.

Neogap's cell therapy can theoretically treat several different types of cancer, but the company will initially focus on advanced colorectal cancer.

For more information, please contact:

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About Neogap Therapeutics

Neogap Therapeutics is a Swedish clinical-stage biotechnology company that develops personalised immunotherapy for the treatment of cancer using the patient's own cells. The therapy is based on the company's two technologies: PIOR[®], a software using DNA sequencing data from the patient and machine learning to select tumour-specific mutations and EpiTCer[®], a method for proliferating the T cells that recognize the selected tumour-specific target structures. NEOGAP is located at the Center for Molecular Medicine, Karolinska Institutet in Stockholm. For more information, visit the company's website, <u>neogap.se</u>, and follow Neogap on <u>LinkedIn</u>.