

DEVELOPING A BIOLOGICAL ANTI-INFLAMMATORY DRUG WITH FIRST-IN-CLASS POTENTIAL



Market need and potential

Treatment of severe juvenile idiopathic arthritis (JIA) in children and rheumatoid arthritis (RA) in adults typically includes one biological drug targeting the pro-inflammatory cytokine TNF- α , e.g. adalimumab (Humira), etanercept (Enbrel) or infliximab (Remicade). The total market value of these drugs in RA is >20B€. Despite the use of anti- $\mathsf{TNF}\text{-}\alpha$ agents, and more recently the JAK-inhibitor tofacitinib and also other anti-inflammatory drugs there is still a high unmet medical need for new treatment of inflammatory diseases.

A significant number of patients do not respond to, or only respond transiently to TNF- α inhibitor drugs. A report from North America (Corrona Database) revealed that out of more than 6 000 patients that had been treated with one of these biological drugs for at least 6 months, one third had discontinued their treatment after 1 year, and nearly 60% after 3 years. The most common reason was lack of efficacy (36%). New innovative drugs providing a novel mode of action is needed.

Business idea

Lipum aims to fill this gap and has identified a novel target for treatment of chronic inflammatory diseases. The target is a protein denoted bile salt-stimulated lipase (BSSL). We have shown a significant correlation between BSSL concentration in plasma and disease activity score 28 (DAS28) in RA, JIA and psoriatic arthritis patients.

Lipum's therapeutic approach is to develop an antibody that blocks the function of BSSL thereby inhibiting the inflammatory process. BSSL promotes recruitment of inflammatory and immune cells to the site of acute inflammation, which normally helps to control the inflammation. However, when an inflammation (is no longer controlled and) becomes "chronic" this effect of BSSL backfires and instead sustains the inflammation. This makes BSSL a new and so far overlooked target for treatment of chronic inflammatory diseases such as RA and JIA.

The efficacy of our novel treatment has been demonstrated in several different established animal inflammation models. Both animals devoid of BSSL (knockout mice) and animals treated with an antibody directed towards BSSL are effectively protected from disease development and progression.

Competition

Lipum offers an extensive and exceptional scientific knowledge on a new target molecule that has the potential to provide a unique way to treat chronic inflammations.

Beside today's advanced TNF- α inhibitors the pharmaceutical industry invest significant resources on JAK inhibitors and IL-6 inhibitors/antagonists and several Phase II and III studies are in progress. Nevertheless, since Lipums mode of action isn't expected to suppress the immune system it should have less side-effects and it may also be used in combination with drugs already available on the market.

Advantages

- BSSL induces human CD14+ monocyte migration in a dose dependent manner, whereas an anti-BSSL mAb blocks the same, also in a dose dependent manner.
- By using a rabbit anti-mouse BSSL mAb a significantly lower disease progression was shown.
- BSSL deficient knock-out mice are protected against disease progression across several inflammatory diseases.
- Anti-BSSL antibodies does not directly suppress the immune system thus the side-effect profile is likely to be very favorable.

Current status

Lipum is among an exclusive group of EU Horizon 2020 SME Instrument phase 2 beneficiaries and supported with 2.2 M€ for a project started in November 2018.

A lead humanized monoclonal antibody candidate drug has been optimised and selected. The cell line development and production has been initiated. We are now proceeding towards toxicological studies and an IND application for clinical trials to start 2021.

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COMPANY PROFILE

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IPR

"New Method for Treatment of Inflammatory Diseases" has claims that relates to inflammatory disorders, such as RA, JIA, and IBD. It has been granted in the US, Europe, China, Australia, New Zealand, and Canada and is pending in India. In addition, a divisional US patent has been granted and further divisional applications have been filed. A product patent application has been filed on the humanized antibody.

Capital need

We are raising 25 MSEK (2.5 M€) for the work until start of the clinical program in year 2021.

Partnership

We are interested in talking to private and institutional investors on equity investments or out-licensing. Our scientists have an ongoing collaboration with the SciLifeLab in Uppsala, Sweden. In addition, Lipum is also actively seeking competent partners for further development.

Team

Dr. Einar Pontén CEO, Co-founder and CEO of SeQuant AB and CEO of Merck SeQuant AB

M.Sc. Pharm. Ulf Björklund Chaiman Board of Directors, Pharmaceutical industry lead-ership pro - former CEO of Aprea (oncology) & OxyPharma (autoimmunity)

Prof. Olle Hernell

CMO, Board of Directors (Co-founder), Discovered the bile salt-stimulated lipase (BSSL) and its role in inflammation

Prof. Lennart Lundberg Board of Directors (Co-founder), Leadership positions Astra-Zeneca - Target Discovery and Business Development

Ass. Prof. Susanne Lindquist CSO (Co-founder), Expert on anima diseases & 15 yrs research on BSSL dels of inflammatory

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