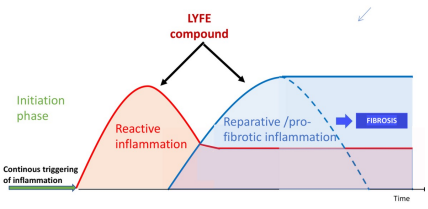
A novel approach for treatment of chronic liver inflammation and fibrosis

Market and potential

Autoimmune hepatitis (AIH) is a special case of chronic liver disease in which the immune system mistakenly attacks the liver cells. AIH affects millions of people worldwide, and there is currently no cure. The available treatments for autoimmune hepatitis, such as immunosuppressive therapy, have limited efficacy and are associated with significant side effects. Therefore, there is an urgent need for new drugs that can target the underlying immune dysregulation that causes AIH and an estimated market value at around USD 200 million.

Business idea

Using a novel drug development platform balancing reactive and regenerative/pro-fibrotic inflammation we have identified a new class of small molecule compounds that can inhibit and reverse inflammation and fibrosis in an *in vivo* animal model.



Our aim is to take new drug candidates through pre-clinical development to the point of first-in-man or potentially through clinical phase 1 trails. Initially, our focus is treatment of the orphan diagnosis (AIH). However, as the MOA is relevant for fibrotic conditions more generally, the long-term goal includes targeting other fibrotic conditions e.g. NAFLD/NASH.

IP

An extended novelty search has revealed patentability of the hit substance and related test substances.

Competition

The competitive landscape for AIH is relatively moderate but rapidly evolving. Several drugs under development are modifications of glucocorticoids and classical immuno-suppressants. A handful of companies are also working on new therapies for AIH.

Most big pharma companies and multiple smaller pharma and biotech companies have drugs under development in the area of NAFLD/NASH. Thus, competition in this area is fierce, but potential revenues are also huge.

Advantages

- Unique platform for balancing reactive and reparative/pro-fibrotic inflammatory responses.
- Novel target and family of compounds interacting with this target.
- *In vivo*, proof-of-concept for a hit compound that efficiently inhibits both inflammation and fibrosis in an animal model for chronic liver fibrosis.
- Orphan designation of AIH
- Huge potential market in other fibrotic conditions e.g. NASH.

Status

- While presently a project at UBI, LYFE Therapeutics is just about to become a company.
- A preclinical drug development plan for taking the candidate compound(s) to FTIM has been established together with SDS Sci.
- Current focus on lead identification and SARs analysis.
- Filing of first patent prepared for Q2 2023.

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Therapeutic area
Autoimmune hepatitis (AIH), Chronic inflammation and fibrosis

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Capital need
Searching for step-wise financing of:

- *In vivo-in vitro* correlation - 1 MSEK
- Pre-clinical non GLP studies – 3-4 MSEK
- Pre-clinical GLP studies and regulatory to FTIM – 15 MSEK