xintelling

Newsletter from Xintela AB

No 1 2024

The development in 2023 & plans for 2024

First of all, I would like to wish you all a happy new year and thank you for your interest and support during the past year. We start the new year by introducing a new newsletter, which we plan to send out to our shareholders at regular intervals to tell you about what is happening in our development projects and in the outside world within our fields of operation. In this newsletter, I will briefly summarize the development of our main projects during 2023 and our plans for 2024.

XSTEM advances in clinical studies

During 2023, Xintela's work has focused on our clinical studies with XSTEM®. Our knee osteoarthritis study in Australia is progressing very well. We have dosed all three dose levels in a total of 24 patients. All three dose levels have been adjudged safe three months after dosing and every six months we analyse various efficacy parameters such as pain and function in the treated joints. It is gratifying that patients report both less pain and better joint function six months after XSTEM treatment. During the coming year, we will continue to analyze efficacy parameters for up to 18 months post-treatment, where we will also use magnetic resonance imaging (MRI) to investigate whether XSTEM can slow down the progression of osteoarthritis and the breakdown of cartilage, bone and other tissues in the joint and also improve the structure and quality of the damaged tissues. We also have the option of expanding the study with up to 30 patients and await further results from the ongoing dose escalation part of the study before making that decision. The primary goal of the study is to show that XSTEM is safe, but we also hope to show a disease-modifying effect of the treatment. An effective treatment for osteoarthritis is highly needed by all those patients affected by this painful and debilitating disease.

Our clinical study on patients with difficult-to-heal venous leg ulcers was a challenge for us during 2023 because we were not prepared for the difficulty of recruiting from this elderly patient group. The study has the primary goal of showing that XSTEM is a safe

VÄSTRA HAMNEN
CORPORATE FINANCE

Analysis monitoring

In the link below you will find the external analyst's report on Xintela and Targinta, "Xintela's integrin marker carries hidden value", published by Västra Hamnen Corporate Finance in early December.

"Xintela's integrin marker carries hidden value"

PDF

treatment. Elderly patients often have other diseases and complications that prevent participation in the study. To handle these issues we have changed different aspects of the study protocol and have also expanded the study by adding three more study clinics. Last month we were able to dose our first patient in the study. We are now very much looking forward to continuing to dose patients with difficult-to-heal venous leg ulcers in 2024 and following them for ten weeks. Our secondary goal is to show that the XSTEM treatment can heal leg ulcers and thus reduce pain and improve quality of life for patients suffering from this disease.

Given the high need for effective disease-modifying treatments for both osteoarthritis and difficult-to-heal leg ulcers, together with our expected clinical results with XSTEM in the coming year, we see opportunities to land commercial agreements already this year. By working with business developers who have extensive international experience in major deals in the life sciences field, we are well prepared to take that step towards commercialization of our technology and products in the near term.

An important part of the commercialization of XSTEM is our GMP-classified production facility. We have an advanced GMP facility and production process, a well-established Quality Management System and an experienced and dedicated team, which has been noted both by the regulatory authorities and in communication with potential partners and licensees. Xintela will produce XSTEM in future partnerships and we are also preparing to provide our GMP cell therapy manufacturing expertise in the development of other advanced therapies.

For those of you with an interest in our veterinary product, EQSTEM®, I can tell you we plan to resume its development as soon as resources permit.

Continued validation of Targinta's cancer target and antibodies

In our subsidiary, Targinta, operations have been at a slow pace during the past year due to limited resources for our oncology projects. Despite this, we have made great strides in our efforts to further validate our patented target molecule, integrin α10β1, and our targeted drug candidates TARG9 and TARG10.

We are now working on completing two manuscripts for publication in scientific journals. These new results give further weight to integrin α10β1 as a unique and important target molecule in the development of both therapeutics and diagnostics for cancer. TARG9 is a so-called Antibody-Drug Conjugate (ADC) in which an antibody is linked to a cytotoxic agent that kills cancer cells that have integrin α10β1 on their cell surface. Our function-blocking antibody TARG10 can also act as an ADC.

In recent years, ADCs have become the hottest therapeutic area in cancer and a very large number of licensing deals have been done in the ADC field. In 2023 alone, over 30 licensing deals have been done between ADC developing companies and large pharma companies. Interestingly, more than half of the agreements are in the preclinical phase, just like TARG9, with upfront payments between USD 23 - 170 million and total values between USD 430 - 1500 million plus royalties. This gives us extra incentive to find a good financing solution for the continued development of Targinta's ADCs and at the same time intensify our work in finding a licensee and/or development partner.

We are looking forward to a very exciting 2024 for both Xintela and Targinta.

With best regards,

Evy Lundgren-Åkerlund
CEO