
Press Release

30 September 2020

Immunicum AB Announces Update on Corporate and Clinical Development Strategy

Immunicum AB (publ: IMMU.ST) announced today an update on the Company's corporate and clinical development strategy. The strategy will be presented by members of the Immunicum management team during the corporate update event today, Wednesday, September 30th starting at 6.00 pm CEST. To view the livestream of the event, click here: <https://www.redeye.se/events/793598/live-strategy-update-immunicum>

“With the information presented today at the corporate update event, we aim to provide an overview of our position as a cell therapy company, discuss strategic opportunities we intend to leverage and confirm our long-term mission for Immunicum,” commented Sven Rohmann, CEO of Immunicum. “Encapsulated, the updated corporate and clinical development strategy is motivated by our goal of building a broad base for generating long-term value for both patients and our committed shareholders.”

Current Company Overview

As a company, Immunicum is first and foremost committed to maximizing the potential of its lead immune primer candidate, ilixadencel, which has now achieved clinical Proof of Concept thanks to the MERECA study. As such, Immunicum is in the right position to start operating with a commercial focus, while taking steps to establishing itself as a cell therapy powerhouse.

Established Proof of Concept

Following the completion of the Phase II MERECA study in kidney cancer patients, Immunicum achieved one of the most important milestones for a biotechnology company: establishing clinical Proof of Concept. To expand on this, Immunicum has demonstrated that ilixadencel facilitates more durable and deeper anti-tumor responses when combined with standard of care. Furthermore, the mechanism of action of this compound is complementary to other available cancer treatments. With a consistently strong safety and tolerability profile, even when combined with other immunotherapies, ilixadencel has the potential to optimize and improve outcomes for patients undergoing standard oncology treatments.

Industry Recognition & Validation

To-date, Immunicum has gained regulatory acknowledgement through an FDA RMAT Designation, EMA ATMP certification and the INN name. Each of these achievements help establish the right framework for ilixadencel to eventually enter the market. In addition, the collaboration with Merck KGaA and Pfizer represents an added level of industry validation for Immunicum's immune primer approach from two leading pharmaceutical companies.

Strong Company Structure

From a management perspective, through the expansion of our Board of Directors before the summer and the appointment of a new CEO in August, Immunicum now has the right experience to bring the Company to the next phase of development and commercialization.

From a financial perspective, through the support of the current shareholders, Immunicum has the financial runway to deliver data-driven value-inflection points through till the end of 2021.

Foundation of Cell Therapy Expertise

As an organization seeking to gain international exposure and attention, Immunicum has assembled a team of highly specialized experts in the field of cell therapy and immunology as well as business to maximize not only ilixadencel's potential, but build a cell therapy company.

Long-term Growth Opportunity

From its current position, Immunicum has the chance to build the right channels to establish long-term growth opportunities, including leveraging a specific strategy to move ilixadencel to patients faster in an indication with a higher Return on Investment and expanding its clinical pipeline to include synergistic cell therapies.

Updated Corporate and Clinical Development Strategy

To effectively move ilixadencel forward in clinical development, maximize the current financial runway and expand Immunicum's clinical pipeline, the Company's management team has identified four core pillars of opportunity upon which a plan will be built to reach its near- and long-term objectives. These four core pillars represent the Company's updated corporate and clinical development strategy.

GIST/Sarcoma as Orphan Indications – Proven Indication and Proven Combination

As ilixadencel has achieved Proof of Concept in RCC in combination with sunitinib, the next critical step is to identify the right way to accelerate ilixadencel through development, towards the market and ultimately, to patients.

To achieve this, the Company has identified Gastrointestinal Stromal Tumors (GIST) and sarcomas as a development opportunity. These types of cancer develop in the connective tissue, such as muscle and bone. The Company's goal in pursuing these indications is to shorten ilixadencel's path to the market and increase the commercial potential.

From a strategic perspective, evaluating ilixadencel in GIST and sarcomas will enable Immunicum to quickly boost ilixadencel through clinical development as these are rare disease indications with unmet medical need, thereby lowering hurdles to advancing a safe, complementary and potentially effective treatment. In addition, due to the Orphan Drug Designation status of both GIST and sarcomas, the patient population sizes for the clinical trials will be smaller, therefore, Immunicum will be able to evaluate ilixadencel in these indications without a development partner.

In addition, as Immunicum has already gained encouraging data in GIST with different kinase inhibitors, including sunitinib, the Company can efficiently advance to later-stage development by leveraging the Proof of Concept with sunitinib in RCC. To view the detailed final results from the Phase I/II GIST trial published this year in *Cancer Immunology, Immunotherapy*, please refer to the following press release: https://immunicum.se/investors/press-releases/press/?xml_id=2048481

Phase Ib/II ILIAD Trial – Novel Indications and Ongoing Combination

In line with guidance to-date, Immunicum will continue to move forward as planned with the Phase Ib/II multi-indication ILIAD study. Once the Phase Ib portion of the trial is completed in the second half of 2021, Immunicum will be able to enter the Phase II portion of the trial.

The results from this trial will give the Company insight into the combination of ilixadencel with checkpoint inhibitors. In addition, as this trial is being conducted in a diverse range of solid tumor indications, Immunicum will be able to identify options that could fit for the further evaluation of ilixadencel and are most attractive for potential pharma partners.

Renal Cell Carcinoma (Kidney Cancer) – Proven Indication, Novel Combination

Immunicum has identified the opportunity for the advancement of ilixadencel in kidney cancer to test our lead candidate in a triple combination – specifically, ilixadencel combined with PD1 and CTLA4 checkpoint inhibitors.

From a strategic perspective, the Phase II MERECA trial enabled the Company to achieve Proof of Concept and indicated that ilixadencel combined with sunitinib has the potential to support more durable and deeper anti-tumor responses. However, the standard of care in the meantime has shifted to newer immunotherapy combinations with checkpoint inhibitors, one of them being the combination of PD1 and CTLA4. The recently announced preclinical results indicated that the triple combination of ilixadencel, PD1 and CTLA4 could result in even more durable tumor regression and longer patient survival and truly has breakthrough potential for these patients.

From a competitive perspective, kidney cancer is a solid tumor indication that several pharmaceutical companies are currently racing to address. By evaluating ilixadencel in this complementary and potentially more impactful triple combination, the Company can thereby more strategically add value to the investments pharmaceutical companies have already made in this indication and increase its attractiveness for partnering.

To facilitate this strategic development path without requiring a large study immediately, ilixadencel would initially be tested with PD1 and CTLA4 to confirm the safety and anticipated efficacy before moving into a registrational or pivotal study.

Pipeline Expansion – Identifying Next-Generation Cell Therapies

In the meantime, Immunicum will seek to expand its pipeline with the goal of becoming a cell therapy powerhouse. To enable this, the Company will continue to move its preclinical development pipeline forward as well as search for additional, potentially synergistic cell therapies that could complement ilixadencel.

Long-Term Mission

As a company that has achieved Proof of Concept, received validation from regulatory authorities and has created a unique complementary approach to modern immunotherapies, Immunicum is now entering a transition phase to grow into a commercially focused, late-stage cell therapy powerhouse. From a practical standpoint, our main objective is to bring ilixadencel to patients as quickly as possible. Immunicum will now be working on a development plan to implement these strategic pillars. As such, we believe that the redefined corporate strategy will enable us to build real value, and ultimately, bring a strong return on investment to our shareholders.

The information is such information that Immunicum is obliged to make public pursuant to EU Market Abuse Regulation. The information was released for public disclosure through the contact persons detailed below on 30 September 2020 at 6.00 pm CET.

FOR MORE INFORMATION, PLEASE CONTACT:

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ABOUT IMMUNICUM AB (PUBL)

Immunicum is establishing a unique immuno-oncology approach through the development of allogeneic, off-the-shelf cell-based therapies. Our goal is to improve survival outcomes and quality of life by priming the patient's own immune system to fight cancer. The company's lead product ilixadencel, consisting of pro-inflammatory allogeneic dendritic cells, has the potential to become a backbone component of modern cancer combination treatments in a variety of solid tumor indications. Immunicum has evaluated ilixadencel in several clinical trials including the recently completed exploratory Phase II MERECA study in kidney cancer and the Company is moving towards late-stage clinical development. Founded and based in Sweden, Immunicum is publicly traded on the Nasdaq Stockholm. www.immunicum.com