# **Press Release**

26 August 2021

## Immunicum AB (publ) Interim Report April - June 2021

## FINANCIAL SUMMARY FOR THE QUARTER APRIL - JUNE

- Net sales for the period amounted to (-).
- Result for the quarter amounted to KSEK -31,278 (-12,625).
- > Earning and diluted earnings per share totaled SEK -0,19 (-0,18).

## SIGNIFICANT EVENTS DURING THE QUARTER

#### CORPORATE

- Immunicum presented an updated organization and corporate strategy overview at an investor event held on April 22, thereby completing the transition phase of the merger with DCprime.
- At the company's Annual General Meeting (AGM) held on May 4, Hans Preusting was elected a member of the board of directors with re-elections of all former board members apart from Charlotte Erdenius and Steven Glazer, both of whom have stepped down from the board. Christine Lind was re-elected as chairman of the board of directors.
- Immunicum successfully completed a capital raise of approximately SEK 141.2 million through a directed share issue. The net proceeds are to be used for completing ongoing clinical trials, prepare for clinical pipeline expansion, extend process development and preclinical research activities, as well as for general corporate purposes.

## CLINICAL

- Immunicum received an Advanced Therapy Medicinal Product Classification from the EMA for its cancer relapse vaccine candidate, DCP-001.
- Immunicum presented immunomonitoring data from the international Phase II ADVANCE II study, which is testing DCP-001 in acute myeloid leukemia (AML) at the European Hematology Association (EHA) conference.
- The ADVANCE II study is fully enrolled and on track for an additional read-out in Q4 2021.
- Immunicum announced the enrollment of the first patient in the Phase I ALISON study, which evaluates DCP-001 in ovarian cancer.

## PRECLINICAL

- Immunicum expanded its in-house process development activities to include ilixadencel and initiated in-house research activities for developing next-generation immune primers.
- A research collaboration was initiated with the group of Prof. Dr. Nina Bhardwaj at the Icahn School of Medicine at Mount Sinai in New York City.
- Immunicum presented data at the Association of Cancer Immunotherapy (CIMT) and the EHA conferences, supporting the mode of action of its lead programs and providing preclinical validation for potential novel combination therapies.
- Immunicum broadened the basis for its US patent covering the DCOne<sup>®</sup> platform and was issued a new US patent covering novel therapies based on the combination of vaccination and intratumoral immune priming.

## **COVID-19 STATEMENT**

Immunicum has taken measures to enable the continuation of its activities, with minor delays mainly in the planning of its clinical activities, particularly the preparations for the start of the ALISON study, related to Covid-19.

## SIGNIFICANT EVENTS AFTER END OF PERIOD

Immunicum received a positive recommendation by the Data Safety and Monitoring Board (DSMB) for the use of ilixadencel in combination with an immune checkpoint inhibitor, pembrolizumab, based on the ongoing Phase Ib part of the ILIAD clinical study in multiple solid tumor indications.

## FINANCIAL SUMMARY

|                                      | Apr - Jun |         | Jan - Jun |         | Full year |
|--------------------------------------|-----------|---------|-----------|---------|-----------|
| KSEK unless otherwise stated         | 2021      | 2020    | 2021      | 2020    | 2020      |
| Operating profit/loss                | -31,278   | -12,625 | -72,057   | -23,858 | -86,027   |
| Net profit/loss                      | -32,130   | -13,390 | -73,701   | -25,408 | -89,248   |
| Earnings per share, before and after |           |         |           |         |           |
| dilution                             | -0,19     | -0,18   | -0,44     | -0,34   | -1,17     |
| Cash                                 | 211,709   | 25,290  | 211,709   | 25,290  | 167,643   |
| Shareholders equity                  | 716,092   | 5,997   | 716,092   | 5,997   | 661,094   |
| Number of employees                  | 29        | 20      | 29        | 20      | 29        |

### **CEO COMMENT**

In the second quarter of 2021, Immunicum completed the transition phase of the merger with DCprime and we are now able to reap the full benefits from the combination. Immunicum has become an integrated, international organization with an advanced clinical pipeline. The Company addresses key challenges in cancer therapy and houses strong R&D capabilities, based on scientific leadership in the field of allogeneic dendritic cell biology. A new focused management team and organization was presented at an investor event held in April and following the AGM in May the supervisory board was strengthened with the addition of Dr Hans Preusting, who brings extensive process development, manufacturing and business expertise. In addition, we completed a directed placement to Swedish and international investors in June, to support ongoing clinical studies, inhouse process development activities, preclinical research programs and general corporate purposes. The financing raised gross proceeds of SEK 141.2 million and benefitted from strong support by existing investors Van Herk Investments and the Swedish AP4 pension fund.

#### Two products - similar underlying biology

Immunicum's clinical pipeline today is based on two products, ilixadencel and DCP-001, with similar underlying, allogeneic dendritic cell biology. The mode of action of these products is based on their capacity to engage the immune system in order to address hard-to-treat established tumors and tumor recurrence, representing two major challenges in cancer therapy. Importantly, their allogeneic nature allows for the development of ilixadencel and DCP-001 as off-the-shelf products, avoiding the complex logistics of autologous cell-based products and allowing for scalable manufacturing. Finally, both products benefit from excellent safety profiles, making them potential candidates for combination therapies and maintenance therapies.

Ilixadencel is an intratumoral immune primer consisting of pro-inflammatory dendritic cells derived from healthy donor material, which are administered directly into the tumor microenvironment in order to render tumors more susceptible to the immune system. Ilixadencel has been tested in a range of difficult-to-treat solid tumors, with promising signs of efficacy in a number of potential indications, including renal cell carcinoma, hepatocellular cancer and gastrointestinal stromal tumors. It has a safety profile which is supportive to combine ilixadencel with other cancer therapies such as tyrosine kinase inhibitors and immune checkpoint inhibitors. The latter was confirmed by the positive evaluation in July by the Data Safety and Monitoring Board of the data from the ongoing ILIAD Phase Ib study, testing ilixadencel in combination with the leading anti-PD1 checkpoint inhibitor Keytruda<sup>®</sup> (pembrolizumab) in multiple solid tumor indications. Immunicum is in the process of evaluating all currently available clinical data for ilixadencel from completed studies and the ongoing ILIAD study to determine, together with clinical experts, the most relevant and

competitive positioning in the cancer therapy landscape. We will provide an update on the clinical development strategy for ilixadencel by the end of 2021.

DCP-001 is a cancer relapse vaccine derived from the proprietary DCOne® leukemic cell line. Tumor recurrence, also called relapse, limits the effectiveness and duration of clinical responses of currently available cancer therapies. Relapse vaccination aims to boost the immune system to control residual disease following initial treatment, in order to prevent or delay relapse. Acute myeloid leukemia (AML) is a blood-borne tumor with a high probability of relapse following initial treatment. A significant group of AML patients cannot undergo a potential life-saving hematopoietic stem cell transplantation, which leaves a largely unmet medical need for novel maintenance therapies. Building on a successful Phase I study, Immunicum is currently conducting the ADVANCE II international Phase II clinical study focused on AML patients with measurable residual disease, which is related to a high probability of relapse. The Company presented immunomonitoring data from the ADVANCE II study at the European Hematology Association conference in June, demonstrating induced systemic immune responses to multiple tumor-associated antigens following DCP-001 vaccination. We also presented preclinical data underlining the combination potential of DCP-001 with currently available and upcoming new therapies 5'-azacytidine and venetoclax. In a humanized mouse model for AML, DCP-001 vaccination led to similar tumor reduction as observed with 5'-azacytidine+venetoclax treatment, whereas the combination of both was the most efficient therapy for disease inhibition. The Company will provide an update of the now fully enrolled ADVANCE II study in the fourth quarter of 2021. In the second quarter of 2021 Immunicum initiated a single-center feasibility study for DCP-001 vaccination in ovarian cancer, which is among the deadliest gynecological cancers due to a high recurrence rate. The study is carried out in collaboration with the renowned group of Prof. Dr. Hans Nijman at the University Medical Hospital in Groningen. The regulatory path for DCP-001 was facilitated by an Advanced Therapy Medicinal Product classification received from the European Medicines Agency in June.

## Continued investments in R&D

Next to developing potential new therapeutic concepts and providing a rationale for novel combination therapies, the Research group focused on advancing our understanding of allogeneic dendritic cell biology. A study describing the interactions between DCP-001 and antigen-presenting cells was presented at the CIMT conference in May, providing further support for the proposed mode of action of DCP-001 and potential new combination therapies with inhibitors of the CD47 pathway, a potential new class of cancer drugs with encouraging signs of efficacy in blood-borne and solid tumors. Next to its in-house research, Immunicum collaborates with academic and industry partners, including ongoing collaborations with PCI Biotech and Glycotope. In the second quarter we expanded our academic network with a research collaboration with the laboratory of Prof. Dr. Nina Bhardwaj at the Icahn School of Medicine at Mount Sinai in New York City, a leading group in the field of human dendritic cell biology. Furthermore, the Company's intellectual property basis was strengthened by broadening the basis for its US patent covering the DCOne<sup>®</sup> platform and a newly issued US patent covering novel therapies based on the combination of vaccination and intratumoral immune priming. As part of the integration process with DCprime, Immunicum transferred the process development activities for ilixadencel to its in-house Process Development group and our expanded R&D department is preparing to move to new facilities in Leiden, The Netherlands in early 2022.

#### Outlook for the second half of 2021

In the past six months, Immunicum has made significant progress in the realization of our ambition to become a fully integrated, biopharmaceutical company addressing key challenges in cancer therapy. We continue on this path with confidence, including the preparations for our new R&D facilities, further updates of our clinical pipeline strategy and a critical clinical read-out from the ADVANCE II study expected in the second half of 2021. As CEO I thank the Immunicum team and all of Immunicum's stakeholders for being part of this journey.

ERIK MANTING Chief Executive Officer

The full quarterly report is available on: <u>http://immunicum.se/investors/financial-reports/</u>

The information contained in this report is that which Immunicum (publ), is obliged to publish in accordance with the Swedish Securities Market Act (SFS 2007:528). The information was submitted for publication, through the agency of contact persons set out below, on August 26, 2021, at 8:00 am CET.

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## ABOUT IMMUNICUM AB (PUBL)

Immunicum is leveraging its unparalleled expertise in dendritic cell biology to develop novel, off-theshelf, cell-based therapies for solid and blood-borne tumors. With complementary therapeutic approaches in Phase II clinical development that are based on intratumoral priming and cancer relapse vaccination, the company aims to improve survival outcomes and quality of life for a broad population of cancer patients. Based in Sweden and the Netherlands, Immunicum is publicly traded on the Nasdaq Stockholm. www.immunicum.com