EDISON

Immunicum

Company update

New CEO and data update from MERECA

Pharma & biotech

Last Friday, Immunicum announced that Sven Rohmann was appointed as CEO with immediate effect. Immunicum has been searching for a new management leader for a while now, with current CSO and co-founder Alex Karlsson-Parra acting as interim CEO. Dr Rohmann brings 30 years of experience as a senior executive at biotech and large pharma companies and has an extensive track record of transactions and fund-raising experience. So, the right CEO at the right time for Immunicum, in our view. These developments follow R&D updates over the summer. The latest follow-up update from the Phase II MERECA trial showed that median OS was reached in the control arm, but not yet in the ilixadencel arm, while the Phase Ib/II ILIAD trial is moving into the non-staggered phase. Our valuation is little changed at SEK2.27bn or SEK24.6 per share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/18	0.0	(97.9)	(1.90)	0.0	N/A	N/A
12/19	0.0	(134.0)	(1.49)	0.0	N/A	N/A
12/20e	0.0	(120.9)	(1.31)	0.0	N/A	N/A
12/21e	0.0	(122.5)	(1.33)	0.0	N/A	N/A

Note: *PBT and EPS are reported.

New CEO appointed with immediate effect

Dr Rohmann holds MD, PhD and MBA degrees and is a very experienced executive with 30 years of experience at biotechnology and large pharma companies including a 10-year career at Merck where he worked on the launch of blockbuster Erbitux. Most recently Dr Rohmann was acting CEO of another listed Swedish biotech, Oasmia Pharmaceutical, which has a commercial stage oncology product with a total out-licensing deal value of $678m. During Dr Rohmann's leadership (2019), Oasmia raised SEK400m. Before that, he was the founding CEO of Ganymed Pharmaceuticals and led the R&D from discovery to Phase II stage. Eventually Ganymed was acquired by Astellas for €422m upfront and €860m in contingent payments. We believe the new CEO has a very relevant skill set for Immunicum, as the company has reached mid-stage and is considering late-stage R&D plans with ilixadencel.

Phase II MERECA and Phase Ib/II ILIAD trial updates

According to the latest (July) follow-up update from the MERECA trial (ilixadencel in renal cell carcinoma; RCC), the mOS was reached at 25.3 months in the sunitinib (control) group, while in the ilixadencel plus sunitinib group the mOS has not been reached yet. In the ilixadencel group, 43% of patients were still alive, vs 33% in the control group. The Kaplan-Meier curves continue to project separation. In another update, Immunicum said that the ILIAD trial is moving into the non-staggered phase after no dose-limiting toxicities were seen in the staggered phase.

Valuation: SEK2.27bn or SEK24.6 per share

Our valuation of Immunicum is little changed at SEK2.27bn or SEK24.6 per share after updating the last reported cash position. As previously, our valuation is based on ilixadencel in multiple indications, with an RCC project revision due after Immunicum releases more details about the next trial.

3 September 2020

Price	**SEK9.8**
Market cap	**SEK905m**

Last reported net cash (SEKm) at Q220	232.2
Shares in issue	92.3m
Free float	90%
Code	IMMU
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(1.3)	(1.1)	34.4
Rel (local)	(3.6)	(9.2)	15.4
52-week high/low	SEK12.1	SEK5.72	

Business description

Immunicum is a clinical-stage immuno-oncology company based in Stockholm, Sweden. It is developing an allogeneic off-the-shelf dendritic cell immune activator or immune primer, ilixadencel, for use in combination with checkpoint inhibitors and other anti-cancer therapies in potentially any solid tumour indications accessible via direct injection.

Next events

Multi-indication Phase Ib (ILIAD) next safety data	End-2020
RCC Phase II (MERECA) next update	Q121

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Edison profile page

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Phase II MERECA study latest follow up

In August 2020, Immunicum published a follow-up update from its Phase II MERECA trial, which enrolled 88 patients (active arm n=58; control arm n=30) with newly diagnosed metastatic renal cell carcinoma (RCC). This is the most advanced trial in the R&D pipeline.

According to the trial design, patients in the active arm received two injections of ilixadencel (on day 1 and day 14), then all patients in both arms underwent kidney tumour surgery. The patients were allowed to recover for six weeks after the surgery before the treatment with Sutent; this gap is mandatory due to Sutent's toxicity. In total, the patients were followed for 18 months (from the first injection of ilixadencel). Subsequently, survival follow-ups are being conducted every six months thereafter.

The first set of data, where the patients were followed for at least 18 months, were presented in September 2019 and the maturing data (at least 24-month follow up) were released in February 2020. The announcement released in August 2020 is the third update from this study with at least 30 months of follow up. Some of the patients were followed for much longer.

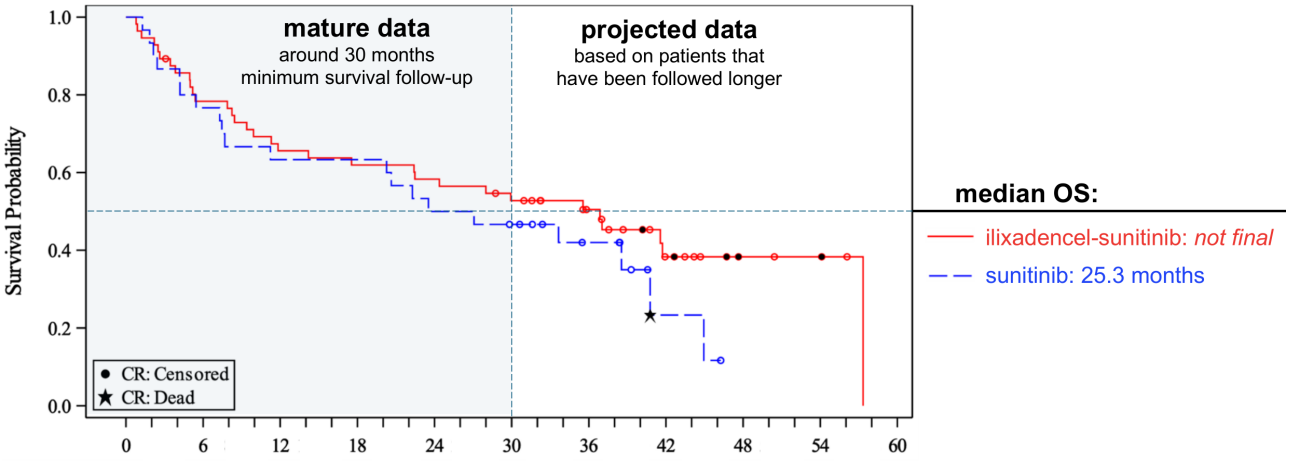
The **primary endpoints** of the study are the hard clinical endpoints of median overall survival (mOS) and overall survival (OS) after 18 months in addition to other **secondary endpoints**, such as objective response rate (ORR), median progression-free survival (mPFS), time-to-progression (TTP), safety and various exploratory endpoints.

In our previous report we described the last update (at least 24-month follow up), which we interpreted as a positive surprise with key primary and secondary endpoints showing promising trends (statistical analysis is not available as the study was not powered to detect efficacy). Data to establish the mOS were still not mature in both arms at that time.

Latest follow-up update from July (at least 30 months)

The mOS was reached at 25.3 months in the control group, while in the ilixadencel group the mOS has not been reached yet. The proportion of patients alive was 43% (24/56) of patients in the ilixadencel treatment group compared with 33% (10/30) of patients in the control group. The Kaplan-Meier curves continue to project separation (some of the patients were followed for much longer than 30 months).

Exhibit 1: Kaplan-Meier curves after each patient was followed for at least 30 months



Source: Immunicum

Next steps

The next 36-month follow up will be released likely in Q121. However, Immunicum is already communicating with the regulatory authorities. Its goal is to get input on the design of the subsequent clinical trial in RCC. To this end, Immunicum benefits from the regenerative medicine advanced therapy (RMAT) designation, which the company was granted in May 2020 for the treatment of metastatic RCC (more details). The advantages of this designation include all the benefits of the fast track and breakthrough therapy designations, such as guidance and frequent interactions with the FDA, increased flexibility in clinical trial design and the possibility of using surrogate endpoints for accelerated approval. Frequent interactions with the regulator and the potential inclusion of surrogate endpoints mean that ilixadencel development timelines could be shorter, which is the key advantage of this designation.

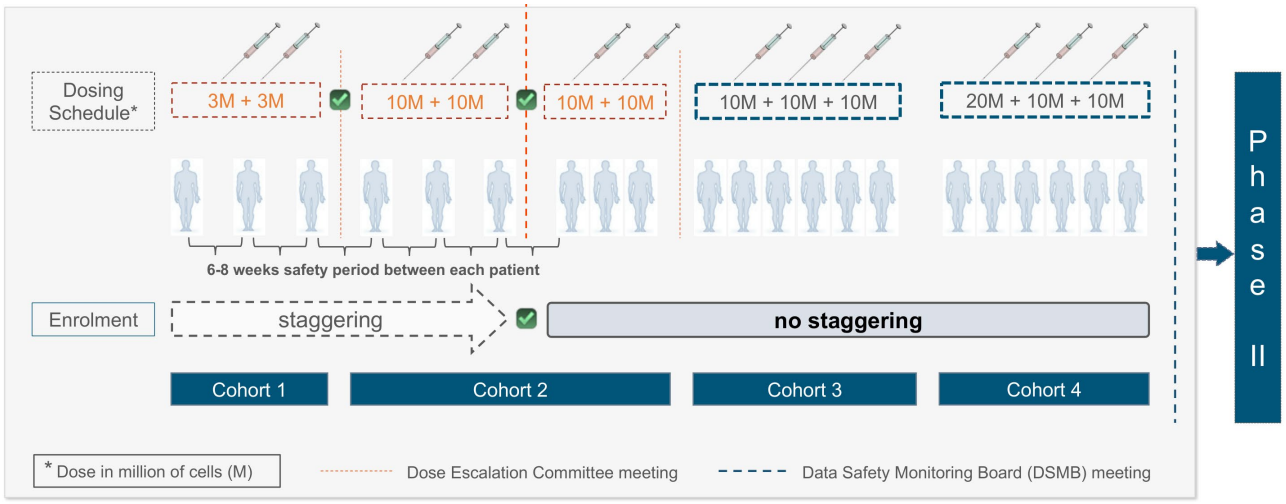
Immunicum indicated that it is continuing discussions with the regulatory authorities to determine the optimal next development steps for ilixadencel. The company has not presented any preliminary design so far, but we understand that all options are on the table (ilixadencel triple combo with checkpoint inhibitors (CPI) and tyrosine kinase inhibitors (TKI) for front-line treatment or ilixadencel with TKI for second-line treatment).

Phase Ib/II ILIAD study update: Moving to non-staggered enrolment phase

In June 2020, Immunicum announced that the sixth patient (Exhibit 2) has completed the safety period in the ongoing Phase Ib/II ILIAD combination trial with ilixadencel and checkpoint inhibitors in various solid tumours. There were no dose-limiting toxicities, which means the study can move into the non-staggered enrolment phase.

The ILIAD study is the first trial where Immunicum is combining its ilixadencel and a checkpoint inhibitor Keytruda (pembrolizumab), therefore the safety data are of interest. A total of 21 patients should be enrolled. So far, six patients have been enrolled in a staggered way with increasing doses of ilixadencel, which means the investigators had to wait six weeks between the enrolments. Since no dose-limiting toxicities were observed, the trial can move into the quicker, non-staggered phase. In total 15 patients are still to be enrolled in the Phase Ib part of the study. Immunicum guides that this can be achieved in H121, although preliminary safety data should be released by end-2020 (depending on COVID-19 pandemic developments). The results are expected in H221.

Exhibit 2: Design of Phase Ib/II ILIAD study



Source: Immunicum

Valuation and financials

Our valuation of Immunicum is only slightly changed at SEK2.27bn or SEK24.6 per share after updating the last reported cash position. As previously, our valuation is based on ilixadencel in multiple indications (described in detail in our last outlook report), which are supported by Immunicum's ongoing R&D programme. We will review our rNPV model for ilixadencel in RCC once more details are known about the next stage of the development following the discussions with regulators and any potential partners.

Immunicum's H120 operating loss was SEK59.0m vs SEK62.3m a year ago, slightly lower as the MERECA study ended in around mid-2019. As usual, R&D costs accounted for the majority of the expense and were SEK41.2m (vs SEK49.0m reported in H119). We keep our estimates unchanged. Immunicum had cash of SEK232m at the end of Q220. Management has previously guided that its cash runway will extend to the end of 2021, which is in line with our model. The potential impact from the ongoing COVID-19 pandemic is difficult to forecast with certainty, but the company indicated that so far operations were not affected. There is some uncertainty about enrolment timelines in the ILIAD trial now that it has moved into the non-staggered phase. This would allow quicker enrolment with more centres active, but opening new centres could be affected depending on how the pandemic develops. The Phase Ib part of the study is still expected to be fully enrolled in H121 with results in H221, so within the existing budget.

Exhibit 3: Sum-of-the-parts Immunicum valuation

Product	Launch	Peak sales ($m)	Probability	rNPV (SEKm)	rNPV/share (SEK)
Ilixadencel – RCC	2026	1,730	25.0%	657.9	7.1
Ilixadencel – HCC	2029	880	20.0%	242.6	2.6
Ilixadencel – NSCLC	2027	1,370	20.0%	643.8	7.0
Ilixadencel – HNSCC	2028	1,900	20.0%	378.4	4.1
Ilixadencel – gastric adenocarcinoma	2028	1,480	20.0%	295.1	3.2
Unallocated costs			100%	(184.0)	(2.0)
Net cash, last reported			100%	232.2	2.5
Valuation				**2,266.0**	**24.6**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations. RCC: renal cell carcinoma; HCC: hepatocellular cancer; NSCLC: non-small cell lung cancer; HNSCC: head and neck squamous cell carcinoma.

Exhibit 4: Financial summary

SEK ('000)	2018	2019	2020e	2021e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT				
Revenue	0	0	0	0
Operating expenses	(98,029)	(133,213)	(121,850)	(123,628)
Depreciation	(5)	(5)	(0)	0
Operating income	184	893	982	1,081
Reported operating profit	(97,845)	(132,325)	(120,868)	(122,547)
Net Interest	(15)	(1,691)	(0)	14
Profit before tax (reported)	(97,860)	(134,016)	(120,868)	(122,533)
Reported tax	0	0	0	0
Profit after tax (reported)	(97,860)	(134,016)	(120,868)	(122,533)
Minority interests	0	0	0	0
Net income (reported)	(97,860)	(134,016)	(120,868)	(122,533)
Basic average number of shares outstanding	51,387	51,387	89,710	92,258
EPS - basic reported (SEK)	(1.90)	(1.49)	(1.31)	(1.33)
BALANCE SHEET				
Non Current Assets	10	252	252	252
Property Plant and equipment, net	9	9	0	(0)
Other financial assets	1	1	1	1
Other Non Current Assets	0	251	251	251
Current Assets	450,362	303,577	182,710	60,163
Cash and cash equivalents	443,798	296,811	175,944	53,397
Accounts receivable	3,307	2,983	2,983	2,983
Marketable securities and short-term investments	0	0	0	0
Prepaid expenses	3,257	3,783	3,783	3,783
Current Liabilities	43,482	30,199	30,199	30,199
Accounts payable	31,266	12,819	12,819	12,819
Accrued other liabilities	11,378	15,736	15,736	15,736
Other current liabilities	838	1,644	1,644	1,644
Non Current Liabilities	850	850	850	850
Long term debt	850	850	850	850
Equity	406,041	272,780	151,912	29,379
CASH FLOW				
Cash Flow from Operations				
EBIT (Operating profit)	(97,845)	(132,325)	(120,868)	(122,547)
Depreciation	58	9	0	(0)
Income Tax paid	0	0	0	0
Other Working Capital changes	(6,867)	(13,485)	0	0
Cash interest paid	(14)	(17)	0	0
Cash interest received	0	10	0	0
Net cash used in Operating activities	(104,668)	(145,808)	(120,867)	(122,547)
Cash Flow from Investing				
Purchase of fixed assets	0	0	0	0
Sale of Investments		(251)	0	0
Net cash used in investing activities	0	(251)	0	0
Cash Flow from Financing				
Change in Capital Stock	419,584	756	0	0
Net cash from Financing activities	419,584	756	0	0
Net Changes in Cash and Cash Equivalent	314,916	(145,303)	(120,867)	(122,547)
Cash and Cash Equivalents - Beginning	128,883	443,799	296,812	173,789
Cash and Cash Equivalents - End	443,799	296,812	173,789	51,256
Net cash/(debt)	442,948	295,961	175,094	52,547

Source: Immunicum accounts, Edison Investment Research

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