EDISON

Immunicum

R&D update

FDA grants RMAT designation

Pharma & biotech

Like many biotechnology companies, Immunicum's share price has undergone a period of volatility, but has now rebounded to its pre-COVID-19 level. To a large extent, this rebound was due to a regenerative medicine advanced therapy (RMAT) designation received from the FDA. It provides the same benefits as a breakthrough therapy designation, so could shorten the development timelines of ilixadencel, Immunicum's allogeneic off-the-shelf dendritic cell immune primer. Although the ongoing COVID-19 pandemic has introduced some uncertainty about timelines, Immunicum should report interesting updates later this year from its both key trials with ilixadencel, Phase II MERECA and Phase Ib/II ILIAD. Our valuation is little changed at SEK2.30bn or SEK24.9 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.

RMAT designation received

On 6 May 2020, Immunicum announced it had received a RMAT designation from the FDA for its lead therapy, ilixadencel, for the treatment of metastatic renal cell carcinoma (RCC). 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 means that ilixadencel development timelines could be shorter, which is the key advantage of this designation.

More news to come from MERECA and ILIAD trials

The most significant recent development and a positive surprise was the 24-month follow-up update from the completed Phase II MERECA trial with ilixadencel in RCC in February 2020. The next check is at 30-month follow-up and should be available mid-2020. The key ongoing Phase Ib/II trial, ILIAD (**ILI**xadencel in combination CPIs in patients with **AD**vanced cancer), is close to completing the staggered phase. If the safety profile is confirmed, the rate of patient recruitment in the trial could increase as early as in Q320 (depending on COVID-19 developments).

Valuation: SEK2.30bn or SEK24.9 per share

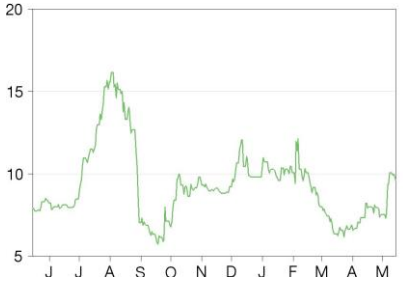
Our valuation of Immunicum is marginally lower at SEK2.30bn or SEK24.9 per share after updating the last reported cash position. With regards to RMAT designation, we will review our rNPV model for ilixadencel in RCC once more details are known about the next stage of the development following the discussions with regulators and any potential partners. Immunicum is well capitalised for a biotech company with cash of SEK263m at the end of Q120. This in particular will be helpful to weather the COVID-19 storm.

15 May 2020

Price	**SEK9.55**
Market cap	**SEK882m**

Last reported net cash (SEKm) at Q120	263.4
Shares in issue	92.3m
Free float	92%
Code	IMMU
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	16.4	(5.1)	21.3
Rel (local)	19.8	20.7	27.0
52-week high/low	SEK16.14	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	Q220
RCC Phase II (MERECA) next update	Mid 2020

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Frequent interactions with FDA and potential surrogate endpoints could translate into faster development

A major advantage of an accelerated development (included in the RMAT designation) is the possibility of using surrogate endpoints. Clinical efficacy trials in RCC can be long if overall survival is the primary endpoint. Using surrogate endpoints, such as durable response, progression-free survival or tumour response, could significantly shorten the time to market. As a next step, Immunicum plans to meet with the FDA and EMA (end-Q220) to discuss the development strategy for ilixadencel in RCC, so no details about the potential further trial design are available yet. We believe partnering discussions will be helped when Immunicum has some clarity on this.

RMAT is a relatively new designation, established in 2017 under the 21st Century Cures Act in the United States. It is meant to expedite the development of regenerative medicine therapies intended to address an unmet medical need. According to requirements, a drug is eligible for RMAT designation if:

- it can be defined as a regenerative medicine therapy (such as cell or gene therapy);
- it is intended to treat a serious condition; and
- preliminary clinical evidence indicates the investigational therapy has the potential to do so.

There are a number of different designations the regulatory authorities can grant to drug developers that have different purposes and the likelihood of receiving the designation differs significantly. For example, the main requirement for orphan drug designation is that the target condition must be rare, in which case the investigational drug would likely be granted the designation. RMAT stands out because more evidence is needed. For example, preliminary clinical efficacy evidence is one of the RMAT requirements. We note that the designation comes after Immunicum presented detailed analysis of the Phase II MERECA trial results and although this cannot be interpreted as a positive review of the MERECA data by the FDA, it satisfied the required hurdle of evidence. According to the FDA own data:

- in 2017, the agency received 31 requests for RMAT, of which only 35% were granted;
- in 2018, 47 requests were submitted, of which 38% were granted; and
- in 2019, 37 requests were submitted, of which 43% were granted.

ILIAD and MERECA trial updates; potential COVID-19 impact

MERECA trial: Next check (30-month follow-up) in mid-2020

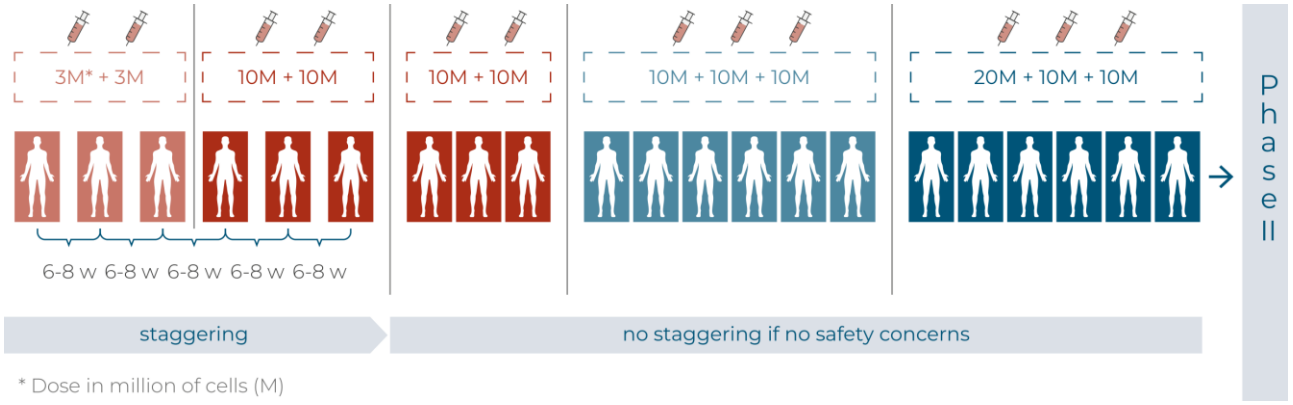
Immunicum's updated results from the Phase II MERECA trial with ilixadencel were a positive surprise. The data were presented at the ASCO-SITC Clinical Immuno-Oncology Symposium in February 2020, which we described in detail in our last report. The maturing data (24-month follow-up) confirmed the separation of the Kaplan-Meier curves, which was projected in September 2019 at the time of the release of the final MERECA results (18-month follow-up). In addition, Immunicum found that a stricter definition of tumour response, the confirmed objective response rate (vs best objective response rate), showed a clear difference between the active and control arms. The next check is at 30-month follow-up and should be available mid-2020.

ILIAD trial summary: Key ongoing trial

Following the completion of the MERECA trial, the main R&D focus is on the ongoing Phase Ib/II study, ILIAD. We described the trial design and the rationale in our previous report. ILIAD is expected to recruit a total of 150 patients in three solid tumour indications: gastric adenocarcinoma (GA) in combination with CPIs, non-small cell lung cancer (NSCLC) and head and neck squamous cell carcinoma (HNSCC).

The Phase Ib part of the study is ongoing, where the patients receive ilixadencel combined with Keytruda. This part is expected to enrol a total of 21 patients (Exhibit 1). The first six patients needed to be enrolled in a staggered format, which in addition to treatment includes a six-week safety period between each patient. This means it will typically take around two-and-a-half to three months between the enrolment of each patient (treatment, safety period, safety committee review). Although this design is relatively slow, it is required when a new combination of two drugs is being tested. If no safety concerns emerge, the rest of the Phase Ib trial will recruit faster. The goal of the Phase Ib part is to assess safety and define optimal dosing in combination with Keytruda.

Exhibit 1: Overall survival and immune response to Tedopi epitopes



Source: Immunicum

On 1 October 2019, Immunicum announced that the first three patients were dosed and no serious adverse events were reported. The second (and the last) cohort of three patients are being treated. This will complete the staggered phase. With its Q120 report Immunicum mentioned that, presuming no new safety issues will appear, the trial could move to the non-staggered phase by the end of Q220 (depending on COVID-19 developments), when more clinical trial sites were planned to be opened so the patients can be recruited faster. All trial sites are in the US so the ongoing COVID-19 pandemic may have some effect on timelines, but it is difficult to predict with certainty at the moment.

The ILIAD trial is important because it will be the first study to test ilixadencel in combination with CPIs. Full safety and efficacy data from the Phase Ib of ILIAD should be released in 2020 or 2021, depending on the COVID-19 impact. The Phase II part of the trial will group patients by indication (HNSCC, NSCLC and GA) into three parallel studies. The controlled efficacy data from the Phase II of ILIAD should be available in 2022.

Valuation and financials

Our valuation of Immunicum is marginally lower at SEK2.30bn or SEK24.9 per share after updating the last reported cash position. With regards to the RMAT designation, 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. 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.

Immunicum's Q120 operating loss of SEK33.9m vs SEK29.1m a year ago indicates a similar level of spending and is in line with our expectations. As usual, R&D costs accounted for the majority of the expense and were SEK23.5m (vs SEK23.2m reported in Q119). We keep our estimates largely unchanged. Immunicum had cash of SEK263m at the end of Q120. 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 even if it causes trial delays, it is likely certain CRO costs could also be delayed, which would act as a mitigating factor.

Exhibit 2: Sum-of-the-parts Immunicum valuation

Product	Launch	Peak sales ($m)	Probability	rNPV (SEKm)	rNPV/share (SEK)
Ilixadencel – RCC	2026	1730	25.0%	657.9	7.1
Ilixadencel – HCC	2029	880	20.0%	242.6	2.6
Ilixadencel – NSCLC	2027	1370	20.0%	643.8	7.0
Ilixadencel – HNSCC	2028	1900	20.0%	378.4	4.1
Ilixadencel – gastric adenocarcinoma	2028	1480	20.0%	295.1	3.2
Unallocated costs			100%	(184.0)	(2.0)
Net cash, last reported			100%	263.4	2.9
Valuation				**2,297.3**	**24.9**

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 3: 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	419,584	756	0
Net Changes in Cash and Cash Equivalent	314,916	314,916	(145,303)	(120,867)
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's account, Edison Investment Research

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