EDISON

Immunicum

Corporate update

Full analysis of MERECA top-line results

Pharma & biotech

The last several weeks have been volatile for Immunicum and illustrate how complicated immunotherapy efficacy trials can be. On 29 August 2019, the company released top-line results from the Phase II MERECA study with ilixadencel plus the tyrosine kinase inhibitor (TKI) sunitinib in renal cell carcinoma (RCC). The co-primary survival endpoint at 18-months lacked positive signals, which led to a negative reaction in the share price. The full analysis released on 25 September 2019 added much more detail, demonstrating that ilixadencel may have a more profound and durable effect (statistical analysis not available), while the survival data may be premature. The next date to watch is January 2020, when Immunicum will report updated survival results at 24 months and median OS if reached. Until then we keep our valuation at SEK2.0bn or SEK21.6/sh.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/17	0.0	(80.3)	(3.1)	0.0	N/A	N/A
12/18	0.0	(97.9)	(1.9)	0.0	N/A	N/A
12/19e	0.0	(119.9)	(1.3)	0.0	N/A	N/A
12/20e	0.0	(121.6)	(1.3)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Top-line results from MERECA trial

Immunicum released Kaplan-Meier plots, which indicate the 18-month cut-off for survival analysis may be premature. Immunicum plans to conduct the next patient survival check once all patients are followed up for at least 24 months and the updated results are expected in January 2020. In the ilixadencel arm, five of 45 evaluable patients (11%) achieved a complete response, while only one of 25 patients (4%) achieved a complete response in the control arm. For comparison, the complete responses achieved by three novel approved treatments for RCC (all combinations include a checkpoint inhibitor) varied between 3.4% and 9.4%.

ILIAD trial to become core R&D programme

Beyond the MERECA study, ongoing Phase Ib/II ILIAD is the next major trial. Initial safety results for the first cohort did not cause any concerns, so the trial is progressing. Although final results from the ILIAD trial are not likely until 2022, safety data from the Phase Ib part are key as it will be the first time ilixadencel is combined with checkpoint inhibitors (CPIs) and will allow the company to engage in negotiations with potential partners before the full ILIAD results are available. There is a theoretical rationale to combine immune primers (specific immune activation) with CPIs (make the tumour visible to immune system). In addition, CPIs have toxicity issues, so when it comes to CPIs and other anti-cancer therapy combinations, safety is as important as efficacy. Thus, ilixadencel's clean safety profile is a benefit.

Valuation: SEK2.0bn or SEK21.6/share

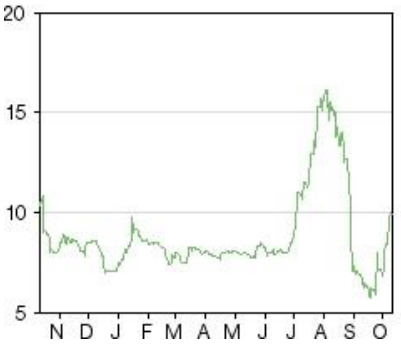
Our valuation is virtually unchanged at SEK2.0bn or SEK21.6/share. At present, we have not made any changes to our underlying assumptions, but we will review them once the mature survival data are in.

11 October 2019

Price	**SEK9.87**
Market cap	**SEK911m**

Last reported net cash (SEKm) at 30 June 2019	363.4
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	54.7	(10.4)	(10.6)
Rel (local)	54.3	(10.2)	(15.0)
52-week high/low	SEK16.14		SEK5.72

Business description

Immunicum is a clinical-stage immunooncology 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

RCC Phase II (MERECA) next survival data	January 2020
Multi-indication Phase Ib (ILIAD) next safety data	Q2 2020

Analyst

Jonas Peciulis +44 (0)20 3077 5728

healthcare@edisongroup.com

Edison profile page

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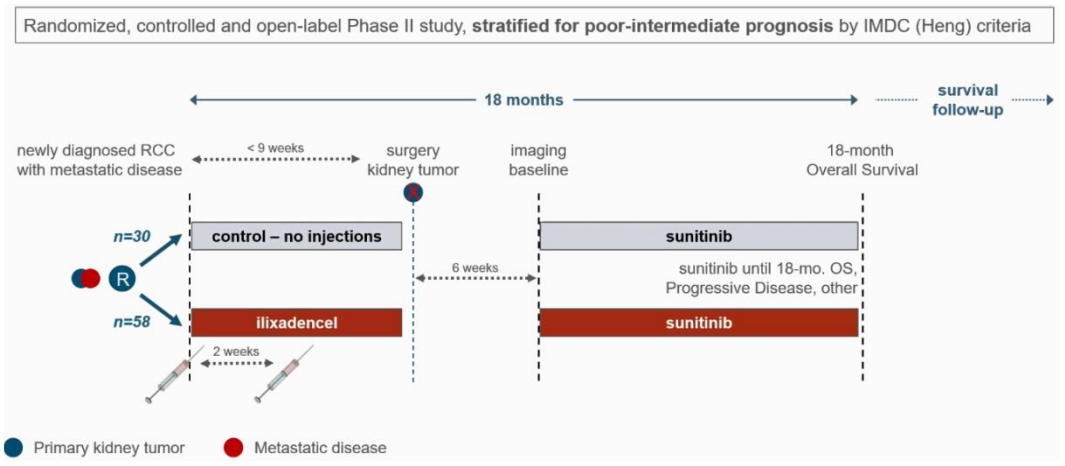
Full Phase II MERECA study results presented

The Phase II MERECA study is the most advanced trial in the R&D pipeline. Patients enrolled for it (n=88) are newly diagnosed and have metastatic RCC, so this is a severely ill group of subjects. The patients were randomised to control (n=30) and active (n=58) arms. 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) according to the trial design. Survival follow-ups will be conducted every six months thereafter.

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 **median progression-free survival (mPFS)**, **time-to-progression (TTP)**, **objective response rate**, **CD8+ T-cell intratumoural infiltration**, **safety** and various exploratory endpoints.

Exhibit 1: Phase II MERECA study design



Source: Immunicum

Top-line results

On 29 August 2019 Immunicum released the initial top-line results from the MERECA trial, while the complete top-line data analysis was released on 25 September 2019. Of the 88 enrolled patients, 70 were evaluable for overall response (RECIST v1.1; ilixadencel n=45 vs control n=25). Immunicum did not provide p values to indicate the statistical significance of the results, quoting that the trial is exploratory and not powered to detect predefined efficacy measures. Therefore, we can only evaluate the numerical differences. Safety and tolerability results were similar in both arms, implying a good safety profile, ie no added toxicity from ilixadencel. The key top-line efficacy results included:

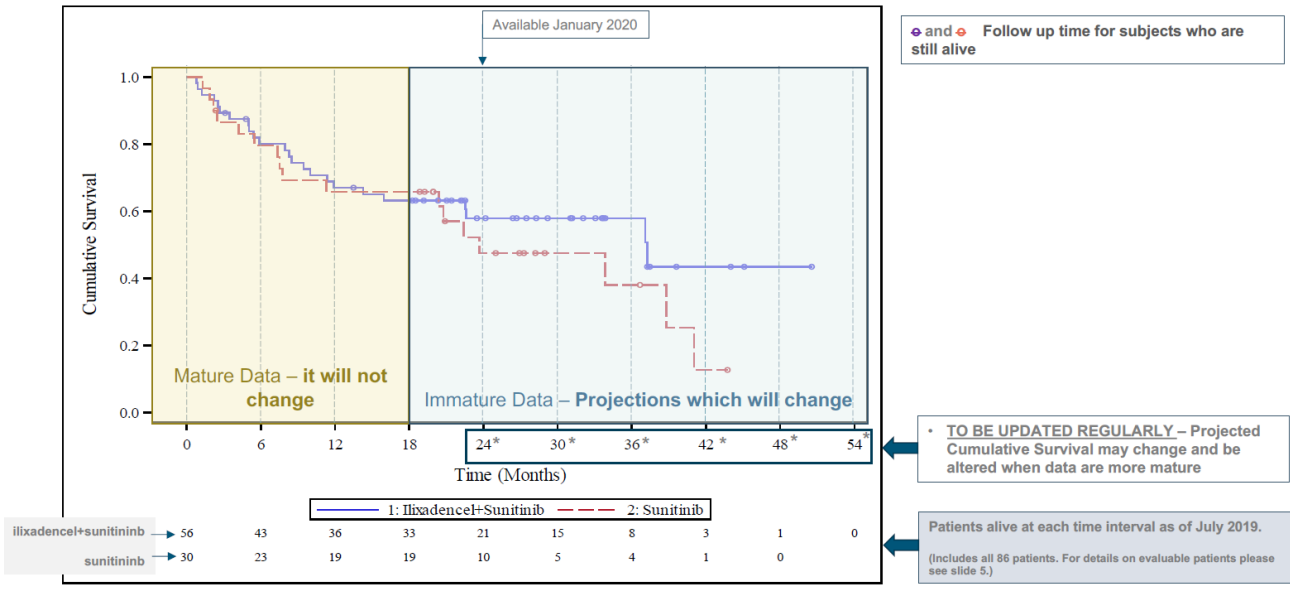
Patient survival

The patient survival rate at the 18-month check was 63% in the ilixadencel arm and 66% in the control group. P values were not provided, but Immunicum's interpretation was that the survival rates between the two arms were similar. Using July 2019 as a cut-off date, 57% of patients in the ilixadencel treatment group were alive compared to 43% in the control group. Immunicum included Kaplan-Meier plots in its presentation (Exhibit 2). This is not that common when the data are not mature, but added a lot more detail. There was no visible separation at the 18-month cut-off point (data are set and will not change); however, the curves started to separate after that point (data are

subject to change). The projected curves will be updated be updated after each patient survival check, so will change. The separation can widen or narrow.

The missed primary endpoint (survival at 18 months) caused the initial negative reaction in the share price. As Immunicum explained, MERECA was an exploratory trial designed to accumulate data and gain insights into the potential efficacy of ilixadencel. The design of such trials, however, is not straightforward, so the sole focus on the primary endpoint alone may not have been an appropriate way to evaluate the MERECA trial results. Therefore, we believe that the additional readout expected in January 2020 will be more definitive than the predefined 18-month survival primary endpoint. Median overall survival has not been reached at the 18-month cut-off, but should be available in the data update.

Exhibit 2: Kaplan-Meier plots (mature in yellow background; projections in blue background, subject to change)



Source: Immunicum

Tumour response

The overall response rate (ORR) was similar in both arms (44% ilixadencel vs 48% sunitinib monotherapy). However, in the ilixadencel arm five out of 45 evaluable patients (11%) achieved a complete response, whereas only one of 25 patients (4%) achieved a complete response in the control arm. Other tumour response measures were also stronger in the ilixadencel arm:

- a longer median duration of response (7.1 months in ilixadencel arm vs 2.9 months in the sunitinib monotherapy arm);
- a higher percentage of responses ongoing at the 18-month check (60% in ilixadencel arm vs 33% in the sunitinib monotherapy group);
- a higher percentage of responders alive at last patient contact (85% in ilixadencel arm vs 58% in the sunitinib monotherapy group).

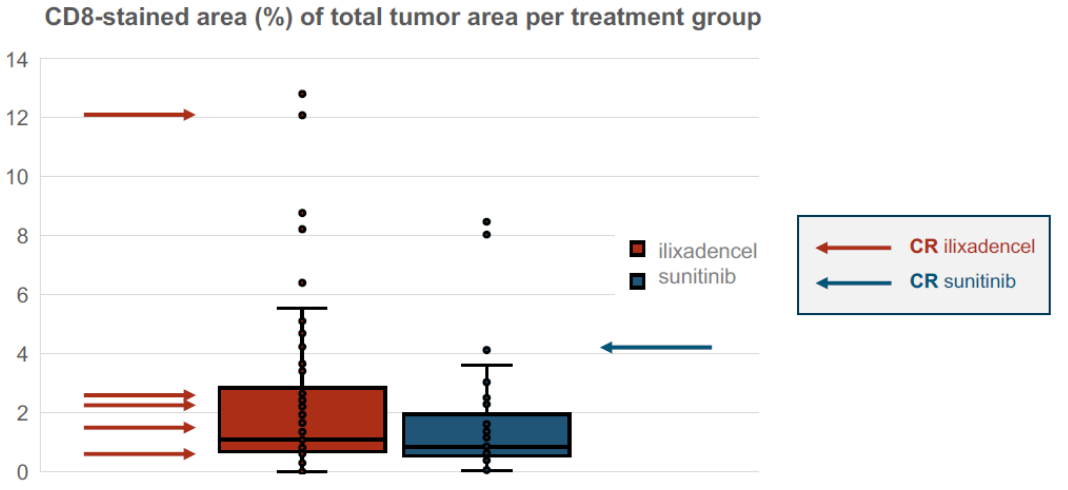
So, while ORR was similar, ilixadencel seems to produce a more profound and more durable effect (numerically, as statistical significance evaluation is not available), which may be clinically relevant findings. For example, the first ever oncolytic virus vaccine, Imlygic (Amgen), which is also thought to act as immune primer, was approved after it demonstrated a durable response rate in melanoma patients defined as a complete or a partial response maintained continuously for a minimum of six months. Imlygic did not significantly improve the overall survival in these patients; however, it was approved by the FDA on the durable response endpoint alone.

Tumour infiltration

Immunicum performed the analysis of tumour tissues from the surgically removed tumours from the patients who received ilixadencel injections and those in the control arm (no treatment before surgery, Exhibit 1). The company decided to use a new method to evaluate the infiltration of CD8+ T-cells. Tissue samples were stained with anti-CD8 antibodies and a new computer algorithm was used to quantify the CD8-stained area as a percentage of the total tumour area. The results showed a median stained area of 1.08% in the ilixadencel group vs 0.84% in the control group, the difference being not significant.

The tumour infiltration assessment method was different than used before, so it is difficult to form any conclusions. Immunicum described that the variability of the CD8-stained area within the treatment groups was very high. The infiltration varied substantially even between tumour samples taken from the same patient or in those patients who demonstrated complete response (Exhibit 3). The novelty of the assessment method and variability in findings make it difficult to evaluate the tumour infiltration results.

Exhibit 3: Tumour infiltration results

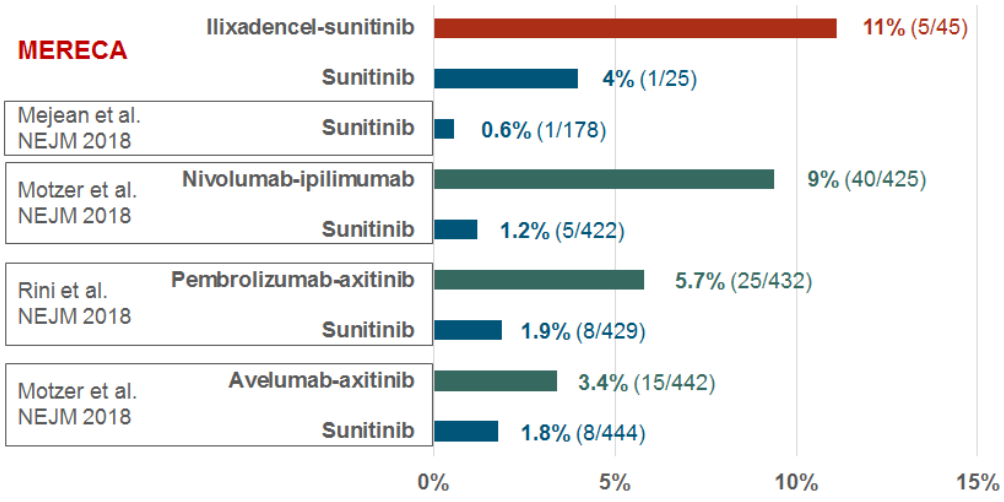


Source: Immunicum

Our view

The complete response result is a standout when compared to other relevant trials in RCC (Exhibit 4). Recently approved new drug combinations for RCC include pembrolizumab (Keytruda; anti-PD-1) plus axitinib (Inlyta; TKI), nivolumab (Opdivo; anti-PD-1) plus ipilimumab (Yervoy; anti-CTLA-4) and avelumab (Bavencio, anti-PD-L1) plus axitinib. All these novel treatment options include CPIs and demonstrated improved overall survival against sunitinib in their respective clinical trials. The 11% response rate seen in the MERECA trial was better than that achieved by axitinib plus CPI, which varied between 3.4% and 5.7%.

Exhibit 4: Cross-trial comparison of complete response rates



Source: Immunicum

Other measures of tumour response were also numerically better in the ilixadencel arm. Better tumour response is a substantial clinical endpoint in itself, but normally this would increase the expectations of an improvement in survival rates. At this stage, the survival endpoints in the MERECA trial either did not provide a positive signal yet (OS) or have not been reached (mOS). The data seem too premature at this stage to draw any final conclusions. The next patient survival check at 24 months should provide a more definite answer (expected in January 2020).

Phase II ILIAD to test combo with CPIs for the first time

Following the readout from the MERECA trial, the main focus will be on the other ongoing Phase Ib/II study, ILIAD (**ILI**xadencel in combination CPIs in patients with **AD**vanced cancer). The study is being conducted in the US and enrolled the first patient in February this year. ILIAD is expected to recruit 150 patients in total in three solid tumour indications: gastric adenocarcinoma in combination with CPIs, NSCLC and head and neck squamous cell carcinoma (HNSCC). The latter indication will be split into two studies with human papilloma virus (HPV) positive and negative tumour types to also study specific immune activation against HPV-related tumours.

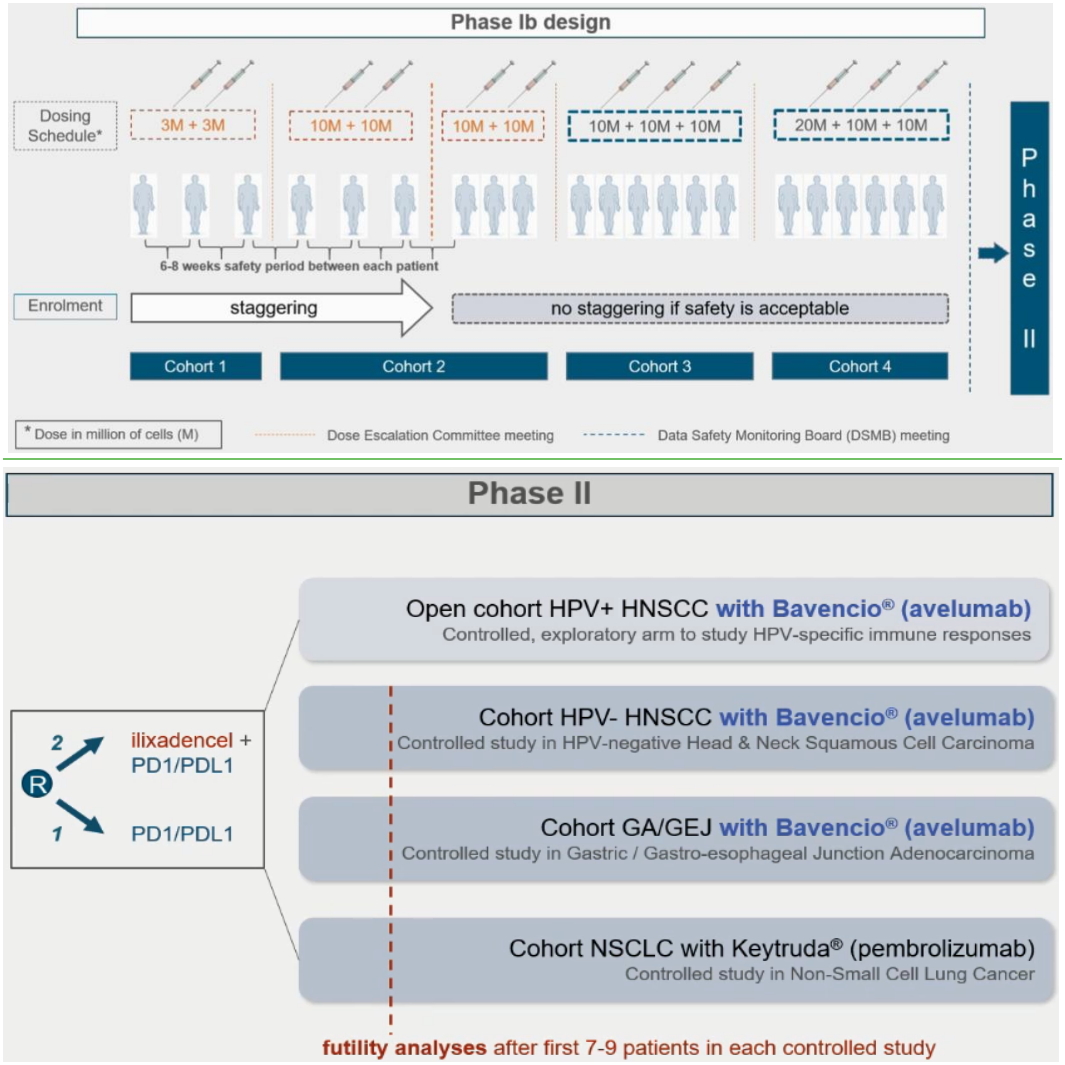
In the Phase Ib part of the trial, ilixadencel will be combined with Keytruda and in the larger Phase II part with Keytruda in NSCLC and Bavencio (avelumab, Merck KGaA and Pfizer) in the other indications. As per the supply agreement, Immunicum will acquire Bavencio at no cost. The interim safety results from the first cohort were announced with no concerns raised. Full safety and efficacy data from the Phase Ib of ILIAD should be released in 2020 and controlled efficacy data from the Phase II of ILIAD should be obtained in 2022. The trial can be broken into two parts:

- The Phase Ib part will enrol a total of 21 patients (Exhibit 5). The first six patients will need 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 such 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 the Phase Ib part is to assess safety and define optimal dosing in combination with Keytruda. On 1 October 2019, Immunicum announced that the first three patients were dosed and no serious adverse events were reported.
- The Phase II part will enrol up to 129 patients who will be grouped by indication (NSCLC, HNSCC and gastric adenocarcinoma). Each of the arms is expected to be sufficiently powered

to detect clinical efficacy. Head and neck cancer patients will be recruited into two studies depending on their HPV tumour type. In total there will be four separate studies ongoing. Immunicum specified that the idea of using two different CPIs in the trial was supported by the FDA. There will be futility analyses after seven to nine patients in each of the controlled trials.

The ILIAD trial is important because it will be the first study to test ilixadencel in combination with CPIs. As well as safety and efficacy data, it is also designed to gather data to demonstrate the proof of mechanism of action by showing that ilixadencel generates a systemic tumour-specific immune response.

Exhibit 5: Phase Ib/II multi-indication CPI combination ILIAD study design



Source: Immunicum

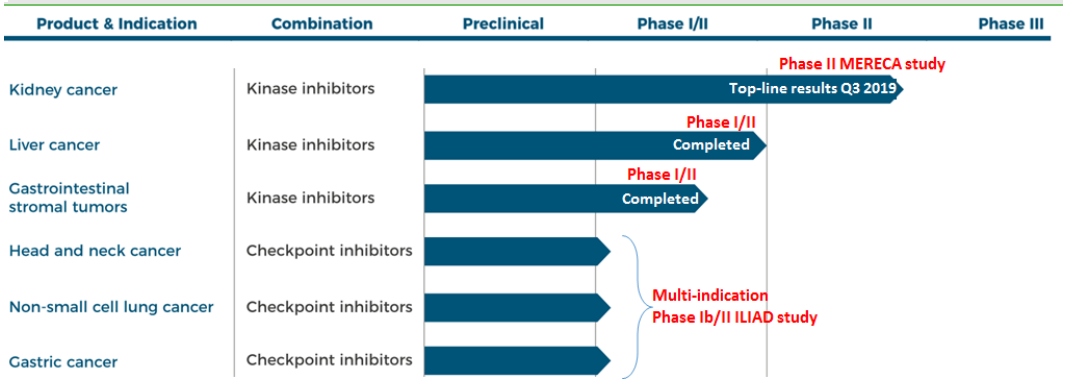
Potential ilixadencel positioning

Ilixadencel is being developed as an immune primer for anticancer treatment combinations. Although the advent of new treatments can cause a paradigm shift in managing patients, it is an unavoidable part of the drug development business. When MERECA was initiated, TKIs such as Sutent were the standard of care and over the last several years three new combination treatments have been approved (as discussed above). Looking forward, CPIs appear to be the best combination partner drugs for Immunicum to explore, although in the 20 August corporate update presentation the company discussed ilixadencel's wider potential beyond CPIs.

CPIs have well-established safety issues, which limit combination potential, so two CPIs can be more effective, but also increase toxicity. Therefore, when it comes to CPI and other anti-cancer therapy combinations, safety is as important as efficacy. From this perspective, immune primers tend to have benign safety profiles, so should combine with CPIs well. Specifically, ilixadencel's safety data have been very good so far.

By the time full safety results from the Phase I part of the ILIAD trial are known (expected in 2020), Immunicum will also have mature data from the MERECA, liver cancer and GIST trials. We believe Immunicum will decide about further development and which indications to prioritise based on the whole dataset. The company expects this type of data package will also be interesting to a number of potential partners and improve the prospects for a potential out-licensing deal.

Exhibit 6: Ilixadencel R&D plan



Source: Immunicum, Edison Investment Research

Financials and valuation

Immunicum's Q219 operating loss of SEK33.2m was higher than the SEK19.3m loss in Q218 and slightly higher than our estimate of SEK30.0m. As expected, R&D costs accounted for the majority of the increase and were SEK25.8m (vs our estimate of SEK23.1m and SEK12.8m reported in Q218), while administrative costs were SEK7.3m vs our expected SEK6.6m and SEK6.4m reported a year ago. The increase in R&D costs was mainly due to the more intensive clinical R&D programme and process development for manufacturing. We have already incorporated increasing R&D in our model and for now keep our estimates unchanged, despite a slightly higher spend than we anticipated. Immunicum is in a transition phase where costs associated with the MERECA trial will wind down, but those associated with the ILIAD trial will increase.

Immunicum had cash of SEK363m at the end of June 2019. Management has guided that its cash runway is to the end of 2021, which is in line with our model. The cash position was substantially improved after the company completed an underwritten fund-raising split between a direct share issue (c SEK178m) and a rights issue (c SEK173m).

Our updated valuation is virtually unchanged at SEK2.0bn or SEK21.6/share. For the time being we have not made any changes to the underlying assumptions in our model (detailed in our last outlook report). The MERECA results were not straightforward to evaluate and one of the key inputs, ie median overall survival, is still missing. We therefore leave our assumptions unchanged until the mature survival data are in.

Exhibit 7: Sum-of-the-parts Immunicum valuation

Product	Launch	Peak sales ($m)	Probability	rNPV (SEKm)	rNPV/share (SEK)
Ilixadencel – RCC	2026	1730	17.4%	425.4	4.6
Ilixadencel – HCC	2029	880	17.4%	230.1	2.5
Ilixadencel – NSCLC	2027	1370	17.4%	563.1	6.1
Ilixadencel – HNSCC	2028	1900	17.4%	343.1	3.7
Ilixadencel – gastric adenocarcinoma	2028	1480	17.4%	270.5	2.9
Unallocated costs			100%	(206.9)	(2.2)
Net cash, end June 2019			100%	363.4	3.9
Valuation				**1,988.8**	**21.6**

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 8: Financial summary

SEK'000s	2017	2018	2019e	2020e	2021e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT					
Revenue	0	0	0	0	0
EBITDA	(80,629)	(97,845)	(119,898)	(121,625)	(123,383)
Operating expenses	(80,847)	(98,029)	(120,101)	(121,848)	(123,627)
Depreciation	(71)	0	(5)	(2)	(1)
Operating income	218	184	202	223	245
Reported operating profit	(80,700)	(97,845)	(119,904)	(121,627)	(123,383)
Net Interest	362	(15)	12	(1)	13
Profit before tax (reported)	(80,338)	(97,860)	(119,891)	(121,628)	(123,370)
Reported tax	0	0	0	0	0
Profit after tax (reported)	(80,338)	(97,860)	(119,891)	(121,628)	(123,370)
Minority interests	0	0	0	0	0
Net income (reported)	(80,338)	(97,860)	(119,891)	(121,628)	(123,370)
Basic average number of shares outstanding	25,959	51,387	89,710	92,258	92,258
EPS - basic reported (SEK)	(3.09)	(1.90)	(1.34)	(1.32)	(1.34)
BALANCE SHEET					
Non Current Assets	105,309	10	5	2	2
Property Plant and equipment, net	69	9	4	1	1
Other financial assets	1	1	1	1	1
Other Non Current Assets	105,239	0	0	0	0
Current Assets	140,837	450,362	307,793	176,709	53,368
Cash and cash equivalents	128,883	443,798	301,064	169,807	46,283
Accounts receivable	0	3,307	3,472	3,646	3,828
Marketable securities and short-term investments	0	0	0	0	0
Prepaid expenses	8,454	3,257	3,257	3,257	3,257
Current Liabilities	55,740	43,482	20,799	11,342	11,369
Accounts payable	11,714	31,266	10,369	912	939
Accrued other liabilities	43,694	11,378	6,836	6,836	6,836
Other current liabilities	331	838	3,594	3,594	3,594
Non Current Liabilities	850	850	850	850	850
Long term debt	850	850	850	850	850
Equity	189,556	406,041	286,150	164,521	(80,477)
Retained earnings start of period	(151,447)	(231,785)	(329,645)	(449,536)	(692,793)
Total Shareholder's Equity	189,556	406,041	286,150	164,521	(80,477)
CASH FLOW					
Cash Flow from Operations					
EBIT (Operating profit)	(80,700)	(97,845)	(119,904)	(121,627)	(123,383)
Depreciation	71	58	5	2	1
Income Tax paid	0	0	0	0	0
Other Working Capital changes	34,455	(6,867)	(22,848)	(9,631)	(155)
Cash interest paid	(274)	(14)	(26)	(26)	0
Cash interest received	0	0	38	25	13
Net cash used in Operating activities	(46,447)	(104,668)	(142,734)	(131,257)	(123,524)
Cash Flow from Investing					
Purchase of fixed assets	0	0	0	0	0
Sale of Investments	10,162	0	0	0	0
Net cash used in investing activities	10,162	0	0	0	0
Cash Flow from Financing					
Change in Capital Stock	62,269	419,584	0	0	0
Net cash from Financing activities	62,269	419,584	0	0	0
Net Changes in Cash and Cash Equivalent	25,984	314,916	(142,734)	(131,257)	(123,524)
Cash and Cash Equivalents - Beginning	102,899	128,883	443,799	301,065	169,808
Cash and Cash Equivalents - End	128,883	443,799	301,065	169,808	46,284
Net cash/(debt)	128,033	442,948	300,214	168,957	45,433

Source: Company accounts, Edison Investment Research

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1,185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia