EDISON

Mendus

Clinical update

Improving survival beyond standard of care

Pharma and biotech

Mendus presented new positive survival data for the company's cancer relapse vaccine, DCP-001, at the 64th American Society of Hematology (ASH) Annual Meeting, demonstrating the treatment has the potential to significantly affect patient survival as an acute myeloid leukaemia (AML) maintenance therapy. At the median follow-up period of 19.4 months, patients in the Phase II ADVANCE II trial treated with DCP-001 recorded a median overall survival (mOS) of 30.9 months and median relapse-free survival (mRFS) had not yet been reached. In our view, the updated survival results indicate significant potential improvements over the only approved AML maintenance therapy, oral azacitidine, given the latter's existing data. We believe the ADVANCE II data could open the door for Mendus to address other unmet medical needs in AML and other blood-borne cancers. Our valuation of Mendus is unchanged at SEK1.8bn or SEK9.1 per share but we will revisit our assumptions once future development plans are reported.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/20	0.0	(89.2)	(1.17)	0.0	N/A	N/A
12/21	0.0	(133.4)	(0.73)	0.0	N/A	N/A
12/22e	3.2	(130.9)	(0.66)	0.0	N/A	N/A
12/23e	0.0	(138.5)	(0.69)	0.0	N/A	N/A

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

ASH data a win for DCP-001

We see the ASH 2022 survival data presented by Mendus as further support for DCP-001's competitive profile as an AML maintenance therapy. Compared to data for the treatment's main competitor, azacitidine, the significantly extended mOS and (potentially) mRFS are very encouraging, in our view; however, the comparison is limited as there is no control or placebo comparator arm in ADVANCE II. We expect management to provide an update on patient survival once mRFS is reached.

A growing need for effective maintenance therapies

As highlighted at a recent key opinion leader (KOL) event, hosted by Mendus, current standard of care (chemotherapy followed by stem cell transplant) is unsuccessful in the majority of patients, due to the persistence of measurable residual disease (MRD). Hence, there is a clear need for effective maintenance therapies. We see DCP-001's meaningful impact on patient survival and MRD status in the ADVANCE II trial as encouraging support for the treatment's potential use as an important part of maintenance therapy regimens.

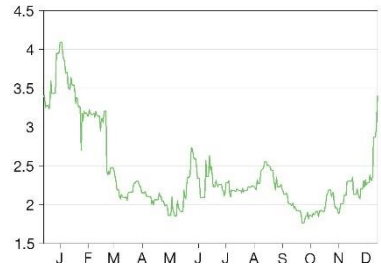
Valuation: SEK1.8bn or SEK9.1 per share

Our valuation of Mendus is unchanged at SEK1.8bn or SEK9.1 per share and includes a net cash position of SEK15.7m at end-Q322. The data from ADVANCE II is undoubtably a positive result for the company, and we will revisit our valuation assumptions for DCP-001 once the full survival results and the company's future development plans are reported.

14 December 2022

Price	**SEK2.37**
Market cap	**SEK473m**
	SEK10.2/US$
Net cash at 30 September 2022 (excluding lease liabilities)	SEK15.7m
Shares in issue	199.4m
Free float	37%
Code	IMMU
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	47.9	74.3	(3.3)
Rel (local)	47.0	62.1	17.4

52-week high/low	SEK4.44	SEK1.76

Business description

Mendus (formerly Immunicum) is a clinical-stage immunoncology company based in Sweden and the Netherlands. The company specialises in allogeneic dendritic cell (DC) biology and currently has two lead cell-based, off-the-shelf therapies for haematological and solid tumours.

Next events

Median relapse-free survival data from ADVANCE II	CY23

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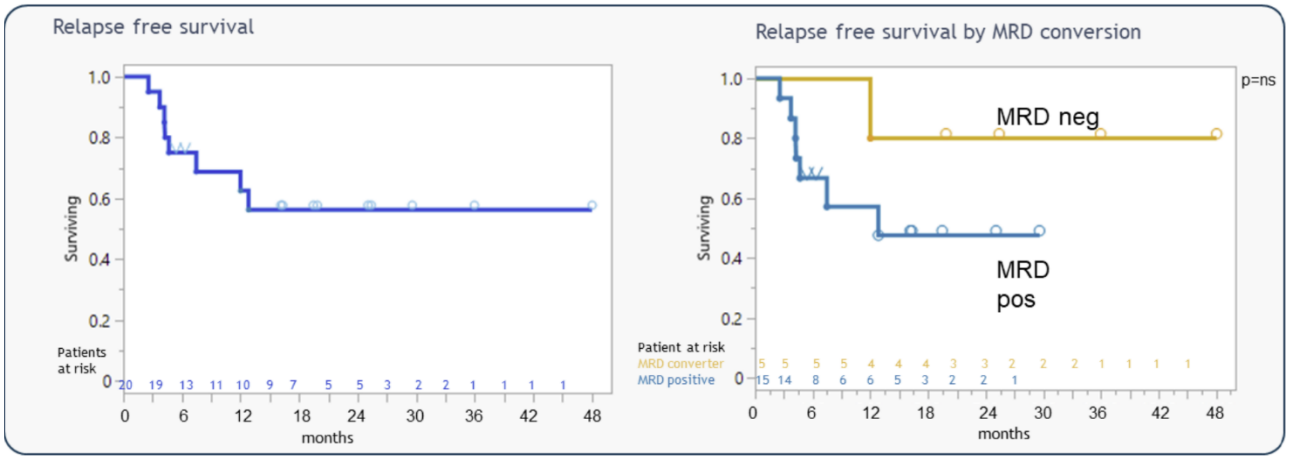
Positive survival data in AML maintenance

The clinical data for DCP-001 as an AML maintenance therapy continue to impress, after Mendus reported updated survival and immunomonitoring data from the Phase II ADVANCE II trial (NCT03697707) at the 64th ASH Annual Meeting. As a reminder, ADVANCE-II is an ongoing, open-label Phase II trial investigating DCP-001 as a potential relapse vaccination in AML patients who are in their complete remission but still have MRD. The results reported at ASH 2022 follow interim data from May, which, at the time of analysis, showed an MRD response in seven out of 20 patients (aged 34–79, median 60) treated with DCP-001 over the 32-week study period, with five patients converting from MRD-positive to MRD-negative and two demonstrating an at least 10-fold reduction in MRD. A further seven patients had stable MRD and six patients relapsed during this time. At this point the study had not yet reached median RFS or OS.

Results presented at ASH 2022 showed that, at a median follow-up period of 19.4 months, median RFS for the entire patient population was not yet reached (but 12-month RFS was estimated at 64%, range 41–80%, Exhibit 1), and median OS stood at 30.9 months (Exhibit 2) and those patients who were still in complete remission (12 out of 20 patients) had been so for 16 to 47 months after start of treatment (Exhibit 1). Patients who had converted to MRD-negative displayed a significantly prolonged RFS and OS, with neither mRFS nor mOS being reached in this sub-group. DCP-001 continued to display a good safety profile, with no serious or severe adverse events reported (the main adverse events continued to be injection site reactions occurring within 48 hours after treatment). This very important in AML, where the main standard of care is cytotoxic chemotherapy, which is unsuitable for many. Following completion of the initial 70-week follow-up period, patients enrolled in ADVANCE II have now entered a long-term follow up, which we expect will provide median-RFS data, once reached.

Exhibit 1: ASH DCP-001 ADVANCE II RFS data

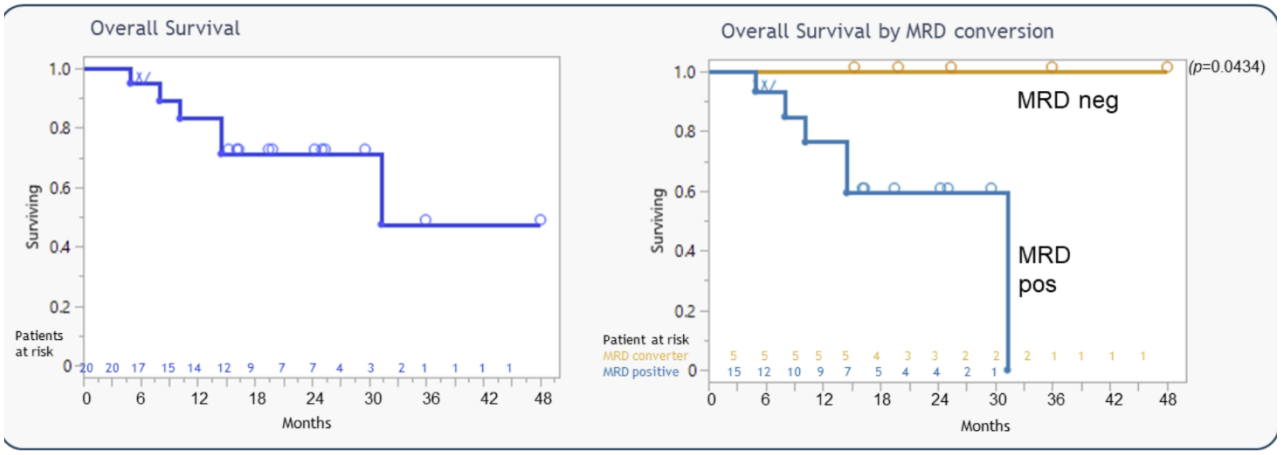


Status per 22nov22: median FU overall population 19.4 months

Median RFS not yet reached: Estimated RFS at 12 months is 64% (41-80%)

Source: Mendus corporate presentation December 2022

Exhibit 2: ASH DCP-001 ADVANCE II OS data



Status per 22nov22; median FU overall population 19.4 months

Current Median OS = 30.9 months (2.6 years): Estimated % OS at 12-months 85,3% (65-94%), Estimated % OS at 24=months 66,3% (40-83%)

Source: Mendus corporate presentation December 2022

Immunomonitoring data, also presented at ASH, showed the number of patients with an MRD response, and the nature of those responses, was unchanged from the preliminary results reported in May (seven of 20 patients, five MRD conversions from positive to negative, two 10x MRD reductions), however 17 out of 20 patients displayed immune responses to DCP-001 specific tumour-associated antigens. High immune responses were observed to correlate with patient MRD responses and the five patients who displayed MRD conversion following DCP-001 treatment had significantly better overall survival, with all being alive at the time of analysis. We believe this represents convincing evidence that DCP-001 can affect a meaningful immune response that may improve patient survival and relapse in AML patients in remission with persistent MRD.

Building a competitive profile versus standard-of-care

The data presented by Mendus demonstrate DCP-001 has the potential to affect a meaningful improvement in patient relapse and survival, in our view. When viewed in comparison with the only approved AML maintenance therapy currently, oral azacitidine (Onureg, Bristol Myers Squibb), this becomes more evident. Onureg was approved by the FDA as an AML maintenance therapy in 2020, based on data from the randomised, placebo-controlled, double-blind Phase III QUAZAR AML-001 (NCT01757535) study, in which the drug demonstrated an mOS of 14.6 months (vs 10.4 months in placebo group) and mRFS of 7.1 months (vs 2.7 months in placebo group) in baseline MRD+ patients. Recent mOS data from the ADVANCE trial (30.9 months) compares very favourably, in our view, with the QUAZAR AML-001 data for Onureg (14.6 months). That the trial has not reach relapse-free survival at a median-follow up period of 19.4 months also suggests significantly improved relapse rates with DCP-001 treatment, in our view, in comparison with the results shown in QUAZAR AML-001. We caveat, however, that comparisons made between clinical trials must be undertaken with care and the design of the QUAZAR AML-001 trial (randomised, placebo controlled, double blind) means direct comparison with the Phase II ADVANCE II study (open-label without a placebo or control comparator arm) survival data is not necessarily applicable.

We note that Venetoclax (AbbVie), a selective B-cell lymphoma 2 (BCL-2) inhibitor, which forms the backbone of many first-line treatment regimens in AML, is also in development as a potential maintenance therapy for AML, in combination with azacitidine. The randomised, double-blind, multi-arm Phase III VIALE-M (NCT04102020) is currently enrolling patients to investigate this combination's effect as a maintenance therapy in AML patients experiencing first remission after chemotherapy. The trial will assess OS and RFS up to three years and is expected to complete in

late-2027. While the potential approval of venetoclax as an AML maintenance therapy could affect DCP-001's commercial prospects, given the toxicity concerns associated with its use (in contrast to DCP-001's good safety profile to date, in our view) we do not see venetoclax as a meaningful threat to DCP-001.

KOL event highlights the need for maintenance therapy

In a recent event, hosted by the company, the need for effective AML maintenance therapies was highlighted by two KOLs in the field. MRD status (defined as the presence of leukaemia cells at levels as low as $1:10^4$ to $1:10^6$ white blood cells) is an emerging prognostic biomarker that is recognised as an important risk factor in AML. In current practice, once AML patients have reached complete remission (CR) through treatment with intensive chemotherapy (eg the 3+7 regimen of three days of anthracyclines followed by seven days of cytarabine), they will either receive a stem-cell transplant (if eligible) or maintenance therapy (currently Onureg) to reduce the risk of relapse. It is estimated that the 3+7 regimen has a 54% CR rate, and while a stem cell transplant is generally recognised as the only curative treatment option but is not always appropriate. It is estimated that the chemotherapy-stem cell transplant standard of care is unsuccessful in 60–80% of patients due to the persistence of MRD, hence the need for effective maintenance therapies. In addition, the event highlighted the shortcomings of immune checkpoint inhibitors and the opening in the treatment landscape this has left, relative to other oncology indications.

Door opening in other haematological malignancies

Considering the recently presented survival and immunomonitoring data and the emerging importance of MRD as a prognostic biomarker for patient survival, we continue to believe that DCP-001 could form an important part of maintenance therapy regimens for AML patients in CR who still harbour MRD. The significant length of patient survival demonstrated in the ADVANCE II trial is especially positive news for Mendus, as the company continues to build DCP-001's competitive profile as an AML maintenance therapy. In addition, we expect this positive data will aid in hastening any licensing/acquisition talks and drawing further industry attention to Mendus's DCOne development platform.

We view the positive data presented at ASH not only as proof-of-concept for DCP-001's use in AML maintenance but for the use of immunotherapy in AML in general (other immunotherapies have historically been ineffective). With this data in hand, we expect the company will assess the full potential impact of DCP-001 in other haematological malignancies. There may now be opportunities for the company to expand the treatment's reach in AML by targeting post-haematopoietic stem cell transplant (HSCT) patients (who are still at risk of relapse), and in combination with azacitidine in both pre- and post-HSCT patients. Management has also communicated that it may consider investigating the use of DCP-001 in other blood-borne malignancies such as myelodysplastic syndromes (MDS) and/or chronic myeloid leukaemia (CML).

Financials and valuation

Our forecasts and valuation, described in our prior note, are unchanged.

Exhibit 3: Financial summary

Accounts: IFRS; Year end 31 December; SEK000s	2019	2020	2021	2022e	2023e
Income statement					
Total revenue	0	0	31	3,212	0
Cost of sales	0	0	0	0	0
Gross profit	0	0	31	3,212	0
SG&A (expenses)	(11,734)	(37,193)	(43,490)	(45,342)	(46,702)
R&D costs	(48,980)	(47,883)	(85,796)	(82,727)	(82,727)
Other income/(expense)	16,689	(64)	(845)	(1,007)	0
Exceptionals and adjustments	0	0	0	0	0
Reported EBITDA	(44,025)	(85,140)	(130,100)	(125,865)	(129,430)
Depreciation and amortisation	(831)	(887)	0	(842)	(4,185)
Reported Operating Profit/(loss)	(44,856)	(86,027)	(130,100)	(126,707)	(133,615)
Finance income/(expense)	(2,915)	(3,220)	(3,310)	(4,200)	(4,894)
Other income/(expense)	0	(1)	0	0	0
Exceptionals and adjustments	0	0	0	0	0
Reported PBT	(47,771)	(89,248)	(133,410)	(130,907)	(138,509)
Adjusted PBT	(47,771)	(89,248)	(133,410)	(130,907)	(138,509)
Income tax expense	0	0	0	0	0
Reported net income	(47,771)	(89,248)	(133,410)	(130,907)	(138,509)
Basic average number of shares, m	73.9	76.2	182.8	199.4	199.4
Basic EPS (SEK)	(0.65)	(1.17)	(0.73)	(0.66)	(0.69)
Diluted EPS (SEK)	(0.65)	(1.17)	(0.73)	(0.66)	(0.69)
Balance sheet					
Property, plant and equipment	4,328	2,909	2,470	12,274	8,966
Intangible assets	0	532,441	532,441	533,859	533,859
Right of use assets	0	0	0	26,177	26,177
Other non-current assets	442	678	843	0	0
Total non-current assets	4,770	536,028	535,754	572,310	569,002
Cash and equivalents	14,032	167,643	155,313	23,874	28,672
Prepaid expenses and accrued income	422	4,760	10,215	10,215	10,215
Other current assets	18,695	20,230	19,702	20,506	20,506
Total current assets	33,150	192,633	185,230	54,595	59,393
Non-current loans and borrowings*	31,062	18,982	36,666	49,752	189,752
Other non-current liabilities	1,230	303	0	24,148	24,148
Total non-current liabilities	32,292	19,285	36,666	73,900	213,900
Trade and other payables	1,898	10,365	11,610	3,112	3,112
Other current liabilities	8,537	22,158	15,657	21,719	21,719
Total current liabilities	11,306	48,282	27,576	27,169	27,169
Equity attributable to company	(5,677)	661,094	656,742	525,835	387,326
Cash flow statement					
Operating Profit/(loss)	(44,856)	(86,027)	(130,100)	(126,707)	(133,615)
Depreciation and amortisation	831	887	992	842	4,185
Other adjustments	0	0	0	0	0
Movements in working capital	(14,186)	27,731	(10,089)	(3,240)	0
Interest paid / received	(166)	(103)	(140)	(4,200)	(4,894)
Income taxes paid	0	0	0	0	0
Cash from operations (CFO)	(57,569)	(56,626)	(138,031)	(132,462)	(134,324)
Capex	(809)	(464)	(1,361)	(12,064)	(878)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	0	0	0	0	0
Cash used in investing activities (CFIA)	(809)	157,298	(1,361)	(12,064)	(878)
Net proceeds from issue of shares	0	0	128,949	0	0
Movements in debt	(760)	(725)	(1,922)	13,086	140,000
Other financing activities	67,818	51,629	0	0	0
Cash flow from financing activities	67,058	50,904	127,027	13,086	140,000
Increase/(decrease) in cash and equivalents	9,627	153,611	(12,330)	(131,439)	4,798
Cash and equivalents at beginning of period	4,405	14,032	167,643	155,313	23,874
Cash and equivalents at end of period	14,032	167,643	155,313	23,874	28,672
Net (debt) cash	(17,030)	133,782	118,647	(25,878)	(161,080)

Source: Edison Investment Research, Mendus company accounts

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