EDISON

Ultimovacs

Clinical data

Data continue to impress in Phase I UV1 study

Pharma & biotech

The highlight of Ultimovacs' Q221 analyst call was the presentation of data from the second cohort of patients enrolled in the Phase I trial in melanoma (UV1 plus Keytruda). This is the first Ultimovacs' trial in the US and the main goals are to gather initial insights on how UV1 combines with a checkpoint inhibitor (CPI) and to test different doses of adjuvant. Ultimovacs has an ongoing Phase II trial in melanoma with a different combination of CPIs. The Phase I trial was therefore not the primary driver in Ultimovacs' investment case until positive first data were presented at this year's ASCO conference in June, which came as a surprise. With the caveat that these are still early-stage results from a Phase I trial, the second set of data announced in August 2021 showed a very similar response, which helps maintain our high expectations Our valuation is increased to NOK4.08bn or NOK128/sh (versus NOK114/sh previously).

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS* (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/19	0.0	(61.2)	(2.67)	0.0	N/A	N/A
12/20	0.0	(120.6)	(3.98)	0.0	N/A	N/A
12/21e	0.0	(152.5)	(4.77)	0.0	N/A	N/A
12/22e	0.0	(159.0)	(4.97)	0.0	N/A	N/A

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

Another set of good data and…

After the minimum 12-month follow-up period, in cohort 2 (n=10) the overall response rate (ORR) was 60% (six out of 10 patients), of which 30% were complete responses (CRs; 3/10), so these results match those in cohort 1 presented at ASCO. The overall survival (OS) rate was 90% after 12 months of follow-up. Median progression-free survival (mPFS) was not reached. The safety and tolerability profile was good and Ultimovacs confirmed that it will continue to use the higher dose of the adjuvant in its ongoing Phase II programme. For comparison, Phase III trials of Keytruda in advanced melanoma and post-hoc analyses after approval show that the ORR was 33–37% and CR 5–12%, with mPFS at 5.5–11.6 months.

…it's only just the beginning

The next catalyst is the 24-month follow up data from cohort 1, which is expected in Q421. The final readout (24 months of follow-up) from both cohorts is expected sometime in 2022. This will be a significant catalyst and set expectations for Ultimovacs' Phase II trial INITIUM (n=154), where patients in the active arm are treated with triple combination UV1 plus nivolumab plus ipilimumab. Readouts are expected in 2022 and 2023 from most or all trials and all are within cash reach, so Ultimovacs is entering an active newsflow period.

Valuation: NOK4.08bn or NOK128 per share

Our updated valuation is NOK4.08bn or NOK128 per share (versus NOK3.65bn or NOK114.1 per share previously). After a second set of strong data, we increase the price of UV1 to $110k per patient per year from $90k in our model (in the US; 50% discount in Europe), which is the main reason for the increase in valuation. For comparison, Keytruda's cost is estimated at $150k in the US. Rolling the model forward largely offsets the lower net cash position.

3 September 2021

Price	**NOK98.9**
Market cap	**NOK3.2bn**

Net cash (NOKm) at end Q221	382
Shares in issue	32.0m
Free float	90%
Code	ULTI
Primary exchange	Euronext Oslo
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	31	19.4	101
Rel (local)	28.3	16.2	52.2
52-week high/low	SEK110.8		SEK47.6

Business description

Ultimovacs is a biotechnology company developing novel immunotherapies against cancer. The lead product candidate, UV1, is a peptide-based vaccine against the universal cancer antigen telomerase (hTERT). Around 85% of all cancer types express high levels of hTERT. Therefore, UV1 has a broad potential in a variety of different settings and combinations with other cancer treatments.

Next events

Cohort 1 24-month follow-up data from Phase I trial of UV1 plus CPI in melanoma	Q421
First patient in Phase II DOVACC	Q321
TENDU Phase I trial with second lead asset interim safety data	Q421
Q321 results	11 November 2021

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Phase I trial in melanoma: Cohort 2 data review

On 12 August 2021, Ultimovacs reported the second set of data from a different group of patients (cohort 2) enrolled into a Phase I trial of UV1 in advanced melanoma in combination with Keytruda. This study is in the US, where Ultimovacs is exploring two different doses of adjuvant to establish its effect on the safety profile (adjuvants can cause rare, but significant allergic reactions). There are two arms with different levels of adjuvant: 37.5µg (cohort 1, 20 patients) and 75µg (cohort 2, 10 patients) (Exhibit 1A). The first set of data from cohort 1 was announced on 19 May 2021 and presented in detail at this year's ASCO conference in June (see our review of the data). The results of the first set of data were:

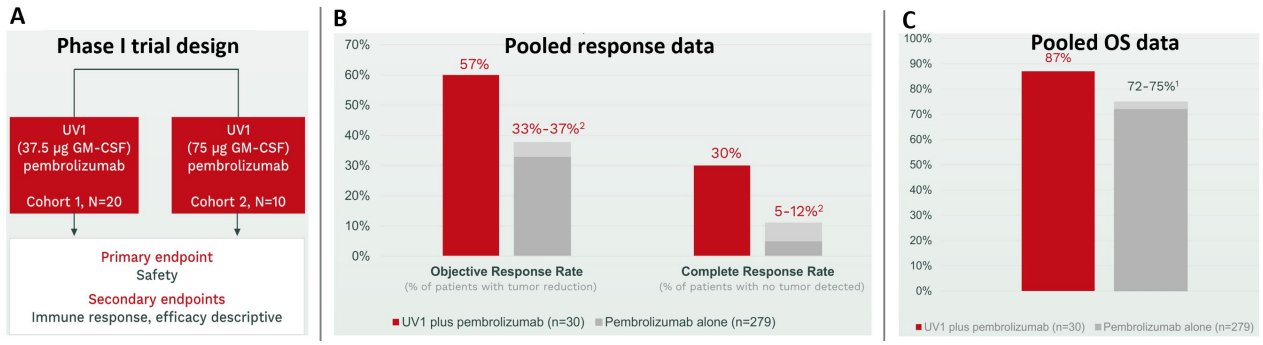
- After the minimum 18-month follow-up period (median of 21 months), **CRs were achieved in 30%** (n=6 out of 20) of patients, where the tumour was reduced to an undetectable level. Partial responses were seen in another five patients, resulting in **55% ORR** (11 out of 20). Note that one patient with a partial response in cohort 1 was reclassified to stable disease after the original press release.
- The median **mPFS was 18.9 months** and **the OS was 85%** (after 12 months of follow-up).

The second set of data announced on 12 August include:

- After the minimum 12-month follow-up period, in cohort 2 (n=10) **ORR was 60%** (six out of 10 patients), of which **30% were CRs** (3/10), so these results match those in cohort 1.
- **OS rate was 90%** after 12 months of follow-up. The **mPFS was not reached**.
- The safety and tolerability profile was good and Ultimovacs confirmed that it will continue to use the higher dose of the adjuvant in its ongoing Phase II programme.

Exhibit 1 summarises the pooled data from both cohorts.

Exhibit 1: Design and interim data from the Phase I melanoma trial in the US



Source: Ultimovacs. Note: [1, 2]Robert et al, 2019, see text.

Our view

Keytruda's (pembrolizumab, anti-PD-1, Merck & Co; global sales of $14.4bn in 2020, consensus forecast of $27.0bn sales in 2026) development helps to put these results in context. Phase III trials of Keytruda in advanced melanoma and post-hoc analyses after approval showed that the ORR was 33–37% and CR 5–12%, with mPFS at 5.5–11.6 months (Robert et al 2019; FDA label). Therefore, the benefit of the addition of UV1 seems to be very strong. These new data are still at an early stage and the comparison is against historical data. However, we find the large difference reassuring. In addition, this second set of results closely follows the first, which gives us confidence in the company's existing R&D strategy (UV1 in combination with CPIs. We note that the scientific rationale for cancer vaccines is to increase the durability of response, so there is potential for overall survival data to surprise again.

Flurry of catalysts ahead

The next catalyst is 24-month follow-up data from cohort 1, which is expected in Q421. The final readout (24 months of follow up) from both cohorts is expected sometime in 2022. This will be a significant catalyst and set expectations for Ultimovacs' Phase II trial INITIUM (n=154), where melanoma patients in the active arm are treated with triple combination UV1 plus nivolumab plus ipilimumab. We also believe there is read across to other cancer types as long as tumours express telomerase and are known to respond to CPI treatment. Readouts are expected in 2022 and 2023 from most or all trials (Exhibit 2) and all are within cash reach, so Ultimovacs is entering an active newsflow period in the next two to three years.

Exhibit 2: R&D pipeline

	Indication	Clinical trial information	Pre-clinical	Phase I	Phase II	Phase III
UV1	First line metastatic malignant melanoma	With pembrolizumab 30 patients		●		
	First line metastatic malignant melanoma	With ipilimumab & nivolumab 154 patients			INITIUM ●	
	Second line mesothelioma	With ipilimumab & nivolumab 118 patients			NIPU ●	
	Second line ovarian cancer	With durvalumab & olaparib 184 patients			DOVACC ●	
	First line head and neck cancer	With pembrolizumab 75 patients			FOCUS ●	
TET	Prostate cancer	Dose finding trials, monotherapy 9-12 patients		TENDU ●		

Source: Ultimovacs

R&D pipeline progress update

Ultimovacs' R&D strategy is to combine UV1 with CPIs due to an expected synergy. The current Phase II programme includes four Phase II trials:

- The **INITIUM trial** (n=154) with UV1 plus ipilimumab and nivolumab in first-line metastatic melanoma. As of 19 August 2021, 68 patients were enrolled versus 40 patients in the Q121 report. The trial is fully sponsored by the company and results are **expected in H222**.
- The **NIPU trial** (n=118) with the same combination as above in second-line mesothelioma. As of 19 August 2021, 38 patients were enrolled versus 29 patients in the previous quarterly report. The trial is led by Oslo University Hospital network, with combination drugs supplied by Bristol-Myers Squibb. Results are **expected in H222**.
- The **DOVACC trial** (n=184) with UV1 plus durvalumab and olaparib in second-line maintenance in ovarian cancer. Regulatory approval is in place, with the first patient expected during Q321. The trial is led by the Nordic Society of Gynaecological Oncology (NGSO) supported by the European Network of Gynaecological Oncological Trial Groups (ENGOT), with drugs supplied by AstraZeneca. Results are **expected in 2023**.
- The **FOCUS trial** (n=75) with UV1 plus standard-of-care pembrolizumab in first-line head and neck cancer. First patient enrolled in July 2021. The trial is led by University of Medicine Halle, part of Martin Luther University. Results are **expected in 2023**.

These trials will enrol a total of more than 500 patients. Approximately 100 patients have been recruited during the past 12 months, which included the peak pandemic months in many Western countries where Ultimovacs has active centres. So, although trial enrolment is still affected by the

pandemic to some extent, overall progress has been good so far. The previously guided readout timelines remain unchanged.

Phase I TENDU: Good safety profile in first cohort of patients

In addition, Ultimovacs has made progress with its second lead asset from the TET platform. Enrolment of the first cohort of three prostate cancer patients to Phase I trial TENDU and treatment with the lowest dose is complete. There were no safety concerns and the trial is enrolling the second cohort of patients, who will be treated with a higher dose.

The platform technology is different from UV1. TET is a first-in-class cancer vaccine solution using the proprietary Tetanus-Epitope Targeting (TET) platform technology. The TET technology represents a new mechanism of action, where vaccine immunisation builds on the patient's existing antibodies from the common tetanus vaccination in childhood. This is a highly differentiated and novel approach that allows adjuvant and vaccine to be incorporated into one molecule.

Valuation

Our updated valuation is NOK4.08bn or NOK128 per share (NOK3.65bn or NOK114.1 per share per share). The emerging picture of UV1 benefit gives us confidence and we increase the cost of UV1 to $110k per patient per year from $90k in our model (in the US market; we apply a 50% discount in Europe), which is the main reason for the increase in valuation (in our last note, after the first set of data were announced, we increased the success probability to 25% from 20%). For comparison, Keytruda's cost is estimated at $150k in the US.

Our valuation is based on risk-adjusted NPV analysis using a 12.5% discount rate, including net cash of NOK382m at end-Q221. Our model includes four rNPV projects, with UV1 being evaluated in Phase II trials in all four indications. We use a bottom-up approach to calculate the market sizes and industry average data for the basis of our other assumptions. More details can be found in our recent initiation report.

Exhibit 3: Valuation of Ultimovacs

Product	Launch	Peak sales* ($m)	NPV (NOKm)	NPV/share (NOK/share)	Probability	rNPV (NOKm)	rNPV/share (NOK/share)
UV1 – malignant melanoma	2028	1,230	3,521.5	110.1	25.0%	1,075.2	33.6
UV1 – mesothelioma	2028	560	1,679.4	52.5	25.0%	531.8	16.6
UV1 – ovarian cancer	2028	764	2,250.9	70.4	25.0%	732.7	22.9
UV1 – H&N cancer	2028	1,330	4,093.5	128.0	25.0%	1,363.0	42.6
Net cash, last reported			381.8	11.9	100.0%	381.8	11.9
Valuation			**11,927.1**	**373.0**		**4,084.6**	**127.7**

Source: Edison Investment Research. Note: Peak sales rounded to the nearest $10m.

Financials

Ultimovacs reports no revenues, while operating spend was NOK70.4m in H121, slightly up from NOK67.4m in H120. The operating spend should increase somewhat in H221, as more Phase II trials have been initiated. This is reflected in our forecasts for total opex of NOK157m and NOK163m in 2021 and 2022, respectively, versus total spend of NOK124m in 2020.

The company had cash of NOK382m at the end of Q221 and no debt. According to Ultimovacs, and in line with our model, the cash will be sufficient to fund budgeted activities until 2023. By that time, readouts from all four Phase II trials should be announced, which will be significant catalysts for the share price.

Exhibit 4: Financial summary

Year end 31 December	NOK'000s	2018	2019	2020	2021e	2022e
			IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Total revenues		0	0	0	0	0
Cost of sales		0	0	0	0	0
Gross profit		0	0	0	0	0
SG&A (expenses)		(27,078)	(20,160)	(50,989)	(58,637)	(60,103)
R&D costs		(28,844)	(43,995)	(70,438)	(95,091)	(99,846)
Other income/(expense)		0	0	0	0	0
Exceptionals and adjustments		0	0	0	0	0
Reported EBITDA		(55,922)	(64,155)	(121,427)	(153,729)	(159,949)
Depreciation and amortisation		(601)	(2,063)	(2,720)	(3,114)	(2,991)
Reported Operating Profit/(loss)		(56,523)	(66,218)	(124,147)	(156,842)	(162,940)
Finance income/(expense)		1,242	5,051	3,593	4,322	3,958
Other income/(expense)		0	0	0	0	0
Exceptionals and adjustments		0	0	0	0	0
Reported PBT		(55,281)	(61,167)	(120,554)	(152,520)	(158,983)
Income tax expense		0	0	0	0	0
Reported net income		(55,281)	(61,167)	(120,554)	(152,520)	(158,983)
Basic average number of shares, m		15.6	22.9	30.3	32.0	32.0
Basic EPS (NOK)		(3.55)	(2.67)	(3.98)	(4.77)	(4.97)
Diluted EPS, (NOK)		(3.55)	(2.67)	(3.98)	(4.77)	(4.97)
BALANCE SHEET						
Property, plant and equipment		736	536	377	359	341
Intangible assets		56,418	55,519	64,551	61,737	59,046
Other non-current assets		0	3,523	3,630	3,630	3,630
Total non-current assets		68,135	70,429	80,353	77,521	74,812
Cash and equivalents		115,540	399,607	440,925	299,590	149,304
Trade and other receivables		0	0	0	0	0
Other current assets		6,184	8,004	8,438	8,438	8,438
Total current assets		121,724	407,611	449,363	308,028	157,742
Non-current loans and borrowings*		0	0	0	0	0
Total non-current liabilities		10,981	13,152	13,870	13,870	13,870
Trade and other payables		2,978	11,768	8,611	10,190	9,400
Other current liabilities		15,996	7,164	17,149	17,149	17,149
Total current liabilities		18,974	20,257	27,467	29,046	28,256
Equity attributable to company*		159,904	444,632	488,380	342,637	190,431
CASH FLOW						
Operating Profit/(loss)		(56,523)	(66,218)	(124,147)	(156,842)	(162,940)
Depreciation and amortisation		601	2,063	2,720	3,114	2,991
Other adjustments		0	0	0	0	0
Movements in working capital		5,528	(1,862)	6,395	1,579	(789)
Interest paid / received		0	0	0	0	0
Income taxes paid		0	0	0	0	0
Cash from operations (CFO)		(50,389)	(62,989)	(108,224)	(141,051)	(150,004)
Capex		(513)	(172)	(282)	(282)	(282)
Acquisitions & disposals net		0	0	0	0	0
Other investing activities		1,247	4,490	(455)	0	0
Cash used in investing activities (CFIA)		(3,852)	4,318	(737)	(282)	(282)
Net proceeds from issue of shares		0	344,582	152,933	0	0
Movements in debt		0	0	0	0	0
Other financing activities		0	(1,579)	(1,916)	0	0
Cash from financing activities (CFF)		0	343,003	151,017	0	0
Increase/(decrease) in cash and equivalents		(54,269)	284,067	41,317	(141,333)	(150,286)
Cash and equivalents at beginning of period		169,808	115,539	399,606	440,923	299,590
Cash and equivalents at end of period		115,539	399,606	440,923	299,590	149,304
Net (debt) cash		115,540	399,607	440,925	299,590	149,304

Source: Ultimovacs accounts, Edison Investment Research. Note: *Long-term debt used instead of equity issue.

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