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QuickView

Ultimovacs

Pharma & biotech

20 January 2021

Phase II data from 500+ patients over 2022/23

Ultimovacs' R&D pipeline has been transformed over the past few weeks. Although delayed by the pandemic, the company has delivered on its promise to initiate a third Phase II trial (UV1 durvalumab and olaparib in ovarian cancer) led by investigators, with combination drugs supplied by AstraZeneca. The recent surprise was, however, the fourth Phase II trial (UV1 plus pembrolizumab in head and neck cancer). Ultimovacs is sponsoring its flagship INITIUM trial (UV1 plus ipilimumab and nivolumab in melanoma), while the other three are led by investigators that are top European oncology organisations. So, in our view, it is the ability to forge relationships with different stakeholders that allowed such an expansion of the pipeline and will ensure eventful years in 2022 and 2023.

Intensive newsflow ahead

These trials will enrol a total of more than 500 patients (Exhibit 1). In our view, this amount of a proof-of-concept data will be more than enough to inform the late-stage R&D strategy, but also will be invaluable in partnering discussions. The INITIUM and NIPU trials are already up and running, while the DOVACC and FOCUS trials should start recruiting patients in H121. The result readouts are expected in 2022 and 2023. Proof-of-concept trials carry significant R&D risk (historical pass-through success probabilities are with the 33–54% range). But the pipeline is well diversified now across indications and different combinations and the result readouts are within cash reach, which the investors will find reassuring.

Cost-efficient way of conducting trials

Ultimovacs is sponsoring its flagship INITIUM trial, while the other three are led by investigators, which are top European oncology organisations. Most of the expensive combination immunoncology drugs are either supplied by large pharma companies or standard of care. Even though technically the data will be owned by the investigators, Ultimovacs has been closely involved in clinical trial design with the idea that the company will be able to carry on late-stage development if the data are supportive.

Valuation: EV of NOK2.04bn

At end-Q320, Ultimovacs had a comfortable cash position of NOK453m and no debt. The implied EV is NOK2.04bn. The share price appreciated recently after the announcements of the two new clinical trials. The readouts from all four trials will further provide significant inflection points.

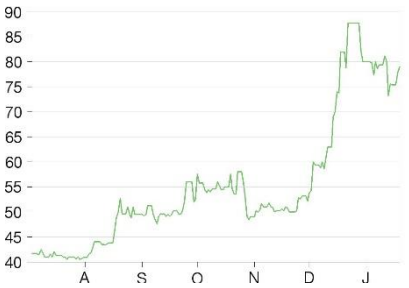
Consensus estimates

Year end	Revenue (NOKm)	PBT (NOKm)	EPS (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/18	0.0	(55.3)	(3.5)	0.0	N/A	N/A
12/19	0.0	(61.2)	(2.7)	0.0	N/A	N/A
12/20e	0.0	(135.0)	(4.2)	0.0	N/A	N/A
12/21e	0.0	(160.0)	(5.0)	0.0	N/A	N/A

Source: Refinitiv

Price	NOK79
Market cap	NOK2.5bn

Share price graph



Share details

Code	ULTIMO
Listing	Oslo Stock Exchange
Shares in issue	32.0m

Business description

Ultimovacs is a biotechnology company focused on developing a near-universal cancer peptide vaccine, UV1, which targets human telomerase reverse transcriptase (known to be expressed in c 85% of cancer types). After successful completion of the Phase I programme, Ultimovacs has initiated a Phase II programme with four clinical trials.

Bull

- UV1 could potentially target multiple cancer types, as telomerase is expressed in 85% of cancers types.
- Comfortable cash position ensures operations into 2023.
- UV1 epitopes were selected based on insights from large clinical trials that investigated another, unrelated telomerase vaccine (ie, based on real-world evidence).

Bear

- COVID-19 pandemic development in Western markets can affect clinical trials, which is true for all drug developers.
- R&D risk is unavoidable in the development of novel cancer therapies.
- Solid immune response data obtained, but clinical proof of concept is yet to be seen (ie, Phase II trials are ongoing).

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R&D pipeline with more than 500 patients in Phase II

In our last report, we provided general background about the company and its lead asset UV1, which is potentially a near-universal peptide cancer vaccine. The lead asset UV1 activates the immune system to recognise cancer cells that express human telomerase reverse transcriptase (hTERT, or telomerase), which is expressed in over 85% of cancer types. In these malignancies, cell reproduction relies exclusively on hTERT maintaining the length of telomers. For this reason, UV1 has a broad potential in a variety of cancers, in different stages, and in combination with other treatments (combination with checkpoint inhibitor is the key element of the R&D strategy). UV1 has an interesting discovery history. The selection of the peptides of which UV1 is comprised is based on insights from large clinical trials that investigated another, unrelated telomerase vaccine. The patients who lived longest in those trials had specific T cells against three epitopes, of which UV1 consists. So UV1 was constructed using real-world evidence.

The Phase II programme now includes:

- The **INITIUM trial** (n=154) with UV1 plus ipilimumab and nivolumab in first-line metastatic melanoma. The trial is fully sponsored by the company and the **results should be in 2022**.
- The **NIPU trial** (n=118) with same combination as above in second-line mesothelioma. The trial is led by Oslo University Hospital network with the combination drugs supplied by Bristol Myers Squibb. **Results are expected in 2022**.
- The **DOVACC trial** (n=184) with UV1 plus durvalumab and olaparib in second-line maintenance in ovarian cancer. The trial is led by the Nordic Society of Gynaecological Oncology supported by the European Network of Gynaecological Oncological Trial Groups with drugs supplied by AstraZeneca. **Results are expected in 2023**. Recent detailed company webcast with a KOL presentation about the trial can be found here.
- The **FOCUS trial** (n=75) with UV1 plus standard of care pembrolizumab in first-line head and neck cancer. The trial is led by University of Medicine Halle part of Martin Luther University. **Results are expected in 2023**.

Exhibit 1: Ultimovacs' R&D pipeline with more than 500 patients in Phase II

	Indication	Clinical trial information	Preclinical	Phase I	Phase II	Phase III	Partner / Collaboration
UV1	Prostate cancer	*22 patients*. Completed in 2015		●			Oslo University Hospital
	Non-small cell lung cancer (NSCLC)	*18 patients*. Completed in 2016		●			Oslo University Hospital
	Metastatic malignant melanoma	*12 patients*. UV1 in combination with Ipilimumab. Completed in 2016		●			Oslo University Hospital
	Metastatic malignant melanoma	Phase I trial (first line with combination UV1/pembrolizumab) *30 patients*. Enrolment completed in Aug-20		●			
	Metastatic malignant melanoma	**INITIUM:** Phase II proof of concept trial (randomized, first line metastatic malignant melanoma with triple combination ipilimumab/nivolumab/UV1) *154 patients*			●		
	Mesothelioma	**NIPU:** Phase II proof of concept trial (randomized, second line mesothelioma with triple combination ipilimumab/nivolumab/UV1) *118 patients*			●		Bristol Myers Squibb and Oslo University Hospital network
	Ovarian cancer	**DOVACC:** Phase II proof of concept trial (randomized, second line maintenance in ovarian cancer with combination durvalumab/Olaparib/UV1) *184 patients*			●		AstraZeneca and NSGO/ENGOT
	Head and Neck cancer	**FOCUS:** Phase II proof of concept trial (randomized, first line head and neck cancer with combination pembrolizumab/UV1) *75 patients*			●		University Medicine Halle (Saale) / Martin-Luther-University
TET	Prostate cancer	**TENDU:** phase I study to assess the safety of the TET platform		●			
	Various	First-in-class cancer vaccine solutions based on the TET-platform technology	●				

● Completed ● Ongoing

Source: Ultimovacs

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