Analyst Report

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OSE Immunotherapeutics

Euronext Paris: OSE [FR0012127173]

27/06/2017

Estimated price:	€13.51
Share price (€)*	4.62
Market Cap. (€M)*	66.02
Estimated Market Cap. (€M)	194.3
Number of shares (M)	14.4
YTD High/Low (€)	7.47/4.58
3-month average daily vol.	17,900
Free Float	48%
Estimated Net Cash (€M)	20.0

** as of 27/06/2017*

OSE Immunotherapeutics temporarily suspends Phase III patient inclusion in NSCLC

OSE Immunotherapeutics announced the temporary suspension of patient enrollment in the Atalante 1 trial, in accordance with an independent expert committee recommendation. Nevertheless, the company pursues the treatment of patients already included in the Phase III trial and benefiting from Tedopi. The experts noticed an imbalance in the benefit/risk ratio of the experimental group. Taking into account that few patients participating in the Atalante 1 study were recruited, and that they suffer from advanced NSCLC cancer, more data need to be collected to draw meaningful conclusions. Further analysis of the available clinical data will help the company determine whether to continue the trial as originally planned. In light of this piece of news, we decided to introduce a risk factor and to delay the clinical timeline. We adjusted our target price to €13.51/share.

An imbalanced benefit/risk ratio

Tedopi is a cancer vaccine currently evaluated in a Phase III clinical trial in patients suffering from NSCLC. The clinical trial design plans the enrollment of patients with advanced cancer (stage IIIb and IV), who have failed a first-line treatment with chemotherapy, or failed a second-line therapy with checkpoint inhibitors. The Atalante 1 study started in February 2016 in Europe and United-States, and patient inclusion was still ongoing. The trial was expected to include 500 patients and to be completed in 2018.

Tedopi's molecular strategy consists in the education of the immune system to recognize cancer cells as foreign agents to destroy it. Tedopi is the combination of 10 neo-epitopes including 5 of the most expressed cancer antigens. The clinical goal of the current trial is to

demonstrate that Tedopi is able to stabilize cancer development and to increase patient survival. As a reminder, data from the Phase II clinical trial showed Tedopi's ability to effectively treat NSCLC and to increase relative survival. The IDMC (Independant Data Monitoring Committee) noticed that Tedopi may not reduce cancer progression in comparison to chemotherapy and that is probably why they recommended to suspend the inclusion. On the other hand, the safety profile observed in the Phase II was confirmed in the Phase III, demonstrating the good tolerance of the treatment. Therefore, the committee's recommendations raise doubts regarding the efficacy of Tedopi. For these reasons, patients already enrolled will continue to receive their treatment, as the company only decided to temporarily suspend the inclusion of new patients in the trial, pending the IDMC's analysis of current data and patients' profile.

Further analysis to evaluate Tedopi's potential

According to the company, the IDMC committee will further review and evaluate available patients' data to determine whether the trial should be maintained in its current design, or if it should integrate new inclusion criteria, with the possibility of identifying sub-groups. Therefore, these first recommendations could be explained by the insufficient number of patients included, and a lack of statistical significance. If further analyses reveal the absence of correlation between the observed effects and Tedopi, due to a specific patients' profile, then the trial could be re-conducted in its original design. This would indicate that the preliminary results observed are only due to the insufficient number of patient to reach statistical power. On the other hand, if the IDMC concludes that the Tedopi treatment arm lacks evidence of efficacy, the trial could be stopped, due to Atalante 1 failure to reach its primary endpoint. Another possibility is to direct the study on a sub-group of patients that could benefit from Tedopi's therapeutic potential. The committee should pronounce new recommendations in late Q3/early Q4 2017.

OSE Immunotherapeutics should announce its definitive decision concerning the Atalante 1 trial in the next months, with the resumption of patient enrollment in the same conditions, with a new design based on more inclusion criteria (sub-group identification), or the halt of the clinical trial. In the meantime, the study continues according to the clinical protocol for patients already enrolled.

Euronext since Jan. 1st, 2017	
OSE Immuno.	-36.0%
Next Biotech	+3.3%
CAC Healthcare	+15.3%
CAC 40	+7.7%
CAC Small	+17.8%

Valuation

We adjusted our valuation model on OSE Immunotherapeutics, in order to take into account these new elements. Since the IDMC did not provide its definitive conclusions concerning Tedopi's ability to reduce cancer progression (at least, as much as chemotherapy), we decreased the Phase III success probability.

Moreover, because the review of the available data would take some time before the possible resumption of patient enrollment, we decided to delay by a year the results of the Phase III trial, and subsequently, the time-to-market.

We still believe that Tedopi could show medical evidence of efficacy because:
1. of a strong scientific and medical rationale
2. of positive effects demonstrated during the Phase II with a significant increase in patient survival
3. the current patients have been selected because of their advanced stages and cancer progression
4. the imbalance ratio noticed could be uncorrelated to Tedopi and due to the insufficient number of patients (necessary to reach statistical power and conclude with measurable observations).

We expect the next step with the committee recommendations in light of more data. Based on these assumptions, we adjusted our target price on OSE Immunotherapeutics to €13.51/share.

Upcoming news flow

- **H2-2017:** clinical data review and IDMC conclusions concerning Atalante 1
- **H2-2018:** clinical developments of OSE-172, a new generation ICI (immune checkpoint inhibitor)
- **H2-2018:** clinical developments of OSE-127 in autoimmune diseases, an IL-7 inhibitor (license option agreement with Servier)

Financials

Earnings Per Share (€)	2013	2014	2015	2016e	2017e	2018e	2019e
EPS	**-0.03**	**-0.36**	**-0.59**	**0,06**	**0,16**	**0,29**	**0,54**

Income Statement (€M)	2013	2014	2015	2016e	2017e	2018e	2019e
Revenues	0,0	0,0	0,0	10,3	12,1	13,1	17,5
EBIT	-0.3	-2.8	-5.6	0,5	2,7	5,5	10,8
Net Income	**-0.3**	**-2.8**	**-5.6**	**0,8**	**2,3**	**4,2**	**7,7**

Balance Sheet (€M)	2013	2014	2015	2016e	2017e	2018e	2019e
Non-Current Assets	0,0	0.1	0.1	59,8	58,3	56,8	55,3
Current Assets	0.3	1.9	16.9	32,8	29,5	32,5	42,2
Including Cash and Cash Equivalents	*0.3*	*1.1*	*9.3*	*25,3*	*22,1*	*28,8*	*38,6*
Total Assets	**0.3**	**2,0**	**17,0**	**92,6**	**87,8**	**89,3**	**97,6**
Total Equity	**-0.9**	**-0.8**	**14.5**	**64,2**	**66,6**	**70,8**	**78,5**
Non-Current Liabilities	1.1	0.9	0.2	16,0	15,1	14,1	13,2
Current Liabilities	0.1	1.9	2.3	12,3	6,1	4,5	5,9
Total Equity and Liabilities	**0.3**	**2,0**	**17,0**	**92,6**	**87,8**	**89,3**	**97,6**

Cash Flow Statement (€M)	2013	2014	2015	2016e	2017e	2018e	2019e
Cash from operating activites	-0.2	-1.9	-4.6	12,0	-2,7	3,9	10,4
Cash from investing activities	0,0	0,0	-6.2	-0,1	-0,1	-0,1	-0,1
Cash from financing activities	0.3	2.8	19.1	-1,0	-0,5	2,8	-0,5
Change in Cash	**0.1**	**0.8**	**8.2**	**11,0**	**-3,3**	**6,7**	**9,9**

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