# Analyst Report Coverage initiated June 24th, 2015 Aurgalys is contracted by OSE Pharma to provide equity research Jamila El Bougrini, PhD Mickael Dubourd, PhD, SFAF Paris & Evry, France November 11th, 2015

## Estimated €15.25 price:

Share price (€) (as of Nov. 11 <sup>th</sup> , 2015)	9.00
High/Low (€) (since Mar. 30 <sup>th</sup> , 2015)*	12.65/8.40
Market Cap. (€M) (as of Mar. 30 <sup>th</sup> , 2015)*	90.4
Estimated Net Cash (€M)	19.9
Estimated Market Cap. (€M)	153.2
Number of shares (M)	10.05
Estimated price (€)	15.25

\*Since OSE Pharma's IPO on March 30<sup>th</sup>,

15,300

29.7%

3-month average daily

volume

Free Float

# OSE Pharma, all set to begin NSCLC Phase III

With the authorization from 7 European countries, OSE Pharma is now ready to begin the Phase III trial in NSCLC for its lead drug candidate Tedopi. This drug candidate is an immunotherapy against cancer that has already demonstrated efficacy in phase II. Tedopi's Phase III results are expected in 2018. In the past few years, immunotherapy has attracted strong interest with the recent approval of checkpoint inhibitors, which are nonspecific therapies allowing the immune system to be activated. On the other hand, Tedopi's therapeutic approach consists in specifically educating the immune system to target cancer cells. OSE Pharma intends to make the most of its technology by developing Tedopi in multiple cancer indications, as a monotherapy or in combination with checkpoint inhibitors, which could significantly increase its market potential.

## OSE Pharma obtains nod from 7 European countries to initiate Phase III in NSCLC

OSE Pharma announced on November 2nd, 2015, that it has received the green light from 7 European countries to initiate the NSCLC (Non-Small Cell Lung Cancer) Phase III study for Tedopi. OSE Pharma's Tedopi is a subcutaneous immune-oncology therapy consisting in 10 neo-epitopes, specifically directed towards 5 tumor antigens that are commonly found in cancer. For instance, 90% of invasive solid tumors express at least one of the five antigens contained in Tedopi.

Five hundred patients expressing the HLA-A2 receptor, a prerequisite to be Tedopi-responsive, will be included in the NSCLC Phase III study, which will take place in Europe and the US. It will compare Tedopi with the best standard of care (docetaxel or pemetrexed) in second line treatment of advanced or metastatic NSCLC. More than 60% of newly diagnosed NSCLC patients are in an advanced stage of the disease, with a 5-year survival rate of around 15%. OSE Pharma's Phase III results are expected in 2018.

### Tedopi in combination therapy and in other indications

Immuno-oncology has become a key therapeutic approach for cancer, demonstrated by the recent approval of drugs targeting



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Euronext since OSE's IPO. Mar. 30th, 2015

OSE Pharma	-16.7%
Alys France*	+8.4%
Next Biotech	+28.3%
CAC Pharma.&Bio.	-6.2%
CAC 40	-1.6%
CAC Small	+9.5%

<sup>\*</sup> Index of French smallcaps (less than €1B market capitalization at time of inclusion) in the healthcare and life sciences sector, listed on Euronext Paris.

See http://www.aurgalys.com/aurgalys-indices

checkpoint inhibitors. In solid tumors, Yervoy (ipilimumab, \$861 M in sales for 9 months 2015) was approved in 2011 for metastatic melanoma, followed by Keytruda (pembrolizumab, \$352 M in sales for 9 months 2015) and Opdivo (nivolumab, \$467 M in sales for 9 months 2015) for the same indication, in 2014. Opdivo and Keytruda, both targeting the PD-1 immune checkpoint were approved by the FDA in NSCLC in March and October 2015, respectively.

Combining therapies has always been a therapeutic approach for cancer. The recent approval of immune checkpoint inhibitors has led to numerous clinical trials in combination therapy. In October, 2015, he FDA approved the first combination of two checkpoint inhibitors, Yervoy and Opdivo, for metastatic melanoma. Combination therapy represents an attractive clinical development strategy for Tedopi in NSCLC, to maximize the product sales potential in this indication.

OSE Pharma also intends to develop Tedopi in indications for which there is a strong medical need, and for which HLA-A2 has been associated with poor prognosis. One of the 5 tumor antigens targeted by Tedopi also needs to be expressed. Possible indications include colon cancer, ovarian cancer and triple negative breast cancer. OSE Pharma would find a partnership to develop these indications in Phase II clinical trials.

#### Valuation of OSE Pharma

Following this announcement, we decided to maintain our valuation of OSE Pharma at €15.25 per share, as it had already been integrated in our valuation model.

#### **Stock Performance**

Despite the success of the company's IPO, OSE's public debut unfortunately coincided with a downward blip in the biotech sector that caused the stock to close 3.4% below the IPO price. Interestingly, on April 24th, 2015, it seemed that OSE Pharma's share was positively impacted (+4.6%) by the \$1.3B Innate Pharma/AstraZeneca immuno-oncology deal. When the company announced its licensing agreement with Rafa Laboratories (Israel), OSE Pharma's share was trading above its IPO price and reached €11.70, but closed at €10.44, on May 12th, 2015. As with other French Biotech smallcaps, OSE Pharma was negatively impacted by the macroeconomic context (crisis in Greece, slowdown of the Chinese economy, etc.). OSE Pharma's stock lost 3.6% in August and 13.0% in September before stabilizing around €9.00 per share. OSE Pharma's stock gained 10.6% on November 2nd, 2015, after obtaining the approval to initiate the NSCLC phase III study.



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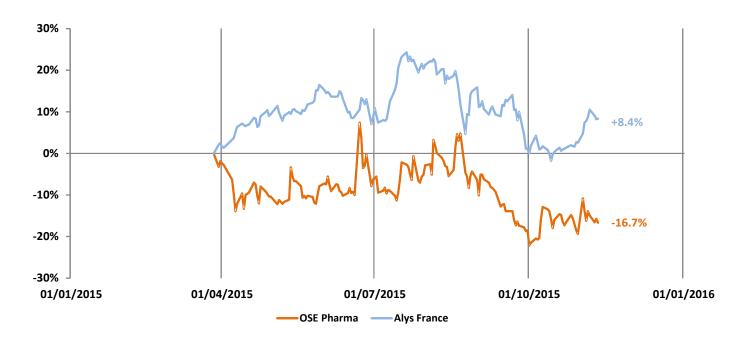


Figure 1: One-year chart dated November 11<sup>th</sup>, 2015, comparing the performance of OSE Pharma's stock with French smallcaps of the life sciences and healthcare sector (Alys France index).

#### **Financial Data**

Earnings Per Shares (€)	2013	2014	<b>2015</b> e	<b>2016</b> e	<b>2017</b> e
EPS	-0,03	-0,36	-0,45	-0,49	-0,64
Income Statement (€M)	2013	2014	2015e	2016e	2017e
Revenues	0,0	0,0	0,0	0,0	0,0
EBIT	-0,3	-2,8	-4,2	-4,9	-6,4
Net Income	-0,3	-2,8	-4,3	-4,9	-6,5
Balance Sheet (€M)	2013	2014	2015e	<b>2016</b> e	<b>2017</b> e
Non-Current Assets	0,0	0,1	0,2	0,3	0,3
Current Assets	0,0	0,8	1,3	1,8	2,3
Cash and Cash equivalents	0,3	1,1	17,5	11,8	4,9
Total Current Assets	0,3	1,9	18,7	13,6	7,2
Total Assets	0,3	2,0	18,9	13,9	7,5
Total Equity	-0,9	-0,8	16,1	11,1	4,7
Non-Current Liabilities	1,1	0,9	0,4	0,3	0,2
Current Liabilities	0,1	1,9	2,9	2,9	3,0
Total Equity and Liabilities	0,3	2,0	19,3	14,3	7,9
Cash Flow Statement (€M)	2013	2014	<b>2015</b> e	<b>2016</b> e	<b>2017</b> e
Cash from operating activities	-0,2	-1,9	-2,6	-4,9	-6,7
Cash from investing activities	0,0	0,0	-0,2	-0,1	0,0
Cash from financing activities	0,3	2,8	19,1	-0,7	-0,1
Change in Cash	0,1	0,8	16,4	-5,7	-6,8



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#### Résumé en français

OSE Pharma a annoncé avoir obtenu l'autorisation de débuter sa phase III pour Tedopi, dans 7 pays européens. Tedopi est une immunothérapie contre le cancer qui utilise 10 néo-épitopes dirigés contre 5 antigènes parmi les plus présents dans les tumeurs solides. Tedopi est actuellement développé dans le cancer du poumon non à petites cellules (NSCLC représentant 85% des cancers du poumon), et l'autorisation obtenue permettra à OSE Pharma de mener un essai de phase III sur 500 patients, atteints de NSCLC, dans plusieurs centres de recherche parmi les plus réputés. Cette étude a pour objectif de démontrer l'efficacité du produit, en particulier dans la prolongation de la survie des patients. Les résultats sont attendus pour 2018, puis un accord avec un partenaire pourrait être conclu pour la distribution du produit dans le cadre de cette première indication. OSE Pharma souhaite étendre l'application de son produit à d'autres indications, telles que les cancers du colon, de l'ovaire et du sein triple négatif. Le potentiel de Tedopi permet également à la société d'envisager une étude du produit en combinaison avec un inhibiteur de checkpoint tel que le Yervoy, Keytruda ou encore Opdivo, dans le NSCLC. Ces stratégies pourraient être développées en Phase II en partenariat avec un laboratoire pharmaceutique. Compte-tenu de son actualité, la valorisation d'OSE Pharma reste identique à celle que nous avions estimée lors de notre dernière analyse, car l'entrée en phase III avait déjà été incluse dans notre modèle.

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#### **About Aurgalys indices**

Aurgalys launched on October 2013, the Alys France index measuring the performance of the 40 French smallcap companies (less than €1B of market capitalization) listed on Euronext/Alternext Paris. Three other indices also measure the performance of companies dedicated to the development of therapeutic molecules (Alys Thérapeutics), diagnostic tests (Alys Diagnostics), medical devices (Alys Medtech) and Greentech (Alys Greenetch). You can find our reports on our website at <a href="http://www.aurgalys.com/aurgalys-indices">http://www.aurgalys.com/aurgalys-indices</a>

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