

OSE Immunotherapeutics (OSE.PA)

OSE Immunotherapeutics Announces Collaboration with Memorial Sloan Kettering Cancer Center for OSE-703 in NSCLC

On June 12th, OSE Immunotherapeutics (EPA: OSE.PA) announced the acquisition of a preclinical candidate called OSE-703 (Effi-3), and a multi-year research collaboration with Memorial Sloan Kettering Cancer Center (MSKCC) to evaluate its potential in solid tumors, including non-small cell lung cancer (NSCLC). OSE-703 is a monoclonal antibody that binds and blocks the interleukin-7 receptor (IL-7R), which is overexpressed in some patients with non-small cell lung cancer (NSCLC) and is linked to a poor prognosis. With the addition of OSE-703, OSE Immunotherapeutics now has 5 assets and expands its oncology portfolio.

- OSE-703 is an IL-7R Targeting Antibody for Solid Tumors.** OSE-703 is a humanized monoclonal antibody that blocks IL-7R signaling by targeting the extracellular domain of the alpha-chain of the IL-7 receptor. IL-7 signaling is required for normal T cell development and survival as well as dendritic cell activation. Alterations in IL-7R signaling have been shown to play a role in the development of acute lymphoblastic leukemia (AML), and is associated with a poor prognosis in NSCLC.

The collaboration with MSKCC aligns with OSE's strategy of partnering its portfolio candidates. In addition to OSE-703, the Company is developing Effi-7 and FR-104 for the treatment of autoimmune disease, and Effi-DEM as an immune checkpoint inhibitor in oncology. Effi-7 is partnered with Servier (private) and FR-104 is partnered with Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson (NYSE: JNJ).

- Collaboration Seeks to Explore Clinical Potential of OSE-703 in NSCLC.** OSE Immunotherapeutics has signed a multi-year collaboration with investigators at MSKCC to study OSE-703 in solid tumors, including NSCLC. Investigators will assess the candidate's efficacy primarily in an NSCLC model. Data from the proposed studies will improve the Company's understanding of OSE-703's potential in treating solid tumors.

Expected Upcoming Milestones

- H1 2017 – DSMB meeting for pivotal Phase III trial for *Tedopi* in HLA-A2+ NSCLC.
- H1 2017 – Publications regarding *Effi-7* and *Effi-DEM*.
- H1 2017 – Initiation of Phase II trial of *Tedopi* in combination with immune checkpoint inhibitors in HLA-A2+ NSCLC.
- 2017 – Evaluation of *Tedopi* in other cancer indications.
- H2 2018 – Phase I clinical trial evaluating *Effi-7*.
- 2018 – Phase I clinical trial evaluating *Effi-DEM*.
- H2 2018 – Topline results of Atalante-1 pivotal Phase III trial for *Tedopi* in HLA-A2+ NSCLC.

Analysts

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Market Data

Price	\$7.15
Market Cap (M)	\$102
EV (M)	\$91
Shares Outstanding (M)	14.3
Fully Diluted Shares (M)	15.0
Avg Daily Vol	9,700
52-week Range:	\$5.67 - \$9.19
Cash (M)	\$25.0
Net Cash/Share	\$0.76
Annualized Cash Burn (M)	\$19.3
Years of Cash Left	1.3
Debt (M)	\$14.1

Financials

FY Dec	2014A	2015A	2016A
EPS H1	NA	(0.34)A	2.44A
H2	NA	NA	NA
FY	(0.39)A	(0.63)A	1.77A

- **OSE-703 is a Potential Therapy for Patients that Overexpress IL-7R.** Depending on the tissue type, IL-7R signaling has been demonstrated to have either anti-tumor or pro-tumor effects. Studies have shown that IL-7 is capable of increasing the number of both cytotoxic CD8⁺ T cells and memory T cells. IL-7R signaling has anti-tumor effects in glioma, melanoma, and prostate cancer. Conversely, IL-7R signaling has also been shown to have pro-tumor effects in lung cancer by preventing apoptosis through the downregulation of BAX, a pro-apoptotic factor. A recent study showed that IL-7R expression was associated with worse outcomes in patients with stage I lung adenocarcinoma. Investigators [reported](#) 5-year recurrence free probability of 76% in IL-7R high expressing patients, compared to 86% in IL-7R low expressing tumors (P=0.001).

Risk to Investment

We consider an investment in OSE Immunotherapeutics to be a high-risk investment. OSE Immunotherapeutics is a development stage company with no history of taking a treatment to market and currently has no FDA or EMA approved drugs in its portfolio. The Company's clinical programs have not yet completed Phase III trials. Furthermore, early indications of efficacy do not necessarily translate into positive late-stage results. Ongoing clinical trials will result in significant additional expenses to the Company and may require additional rounds of dilutive financing. As with any company, OSE Immunotherapeutics may be unable to obtain sufficient capital to fund planned development programs. There are regulatory risks associated with the development of any drug and OSE Immunotherapeutics may not receive FDA or EMA approval for its candidate despite significant time and financial investments. Regulatory approval to market and sell a drug does not guarantee that the drug will penetrate the market, and sales may not meet expectations.

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