OSE Immunotherapeutics (OSE.PA)

OSE and Boehringer Ingelheim Dose 1st Patient in Phase I Study with OSE-172 (BI 765063)

OSE Immunotherapeutics (Paris: OSE) and its partner, Boehringer Ingelheim (BI) (private), announced today that they have dosed the first patient in a Phase I study evaluating their first-in-class anti-SIRPa antibody OSE-172 (BI 765063). The initiation of the study triggered a €15 million ($16.8 million) milestone payment from BI to OSE – representing a source of nondilutive funding for the Company. In parallel, OSE is developing OSE2101 – a neoepitope vaccine – in advanced NSCLC, and OSE-127, an IL-7R antagonist, in healthy volunteers. Data from those studies are expected in YE 2019-Q1 2020, and Q4 2019, respectively, representing the next inflection points for the Company.

- **First Patient Dosed in Phase I study with BI 765063 Triggers a €15M Milestone Payment.** OSE reported that the first patient in a dose finding study with BI 765063 has been treated (trial centers are based in France and Belgium), which prompted a previously agreed upon €15 million ($16.8 million) milestone payment to OSE from its partner BI. The study is evaluating BI 765063 as a monotherapy, and in combination with BI's anti-PD-1 therapy, BI 754091, in patients with advanced solid tumors. We await topline data from this study, as it will be the first to give us a glimpse as to the feasibility of targeting SIRPa versus CD47 – SIRPa's ligand – which is currently being advanced by a plethora of companies.
- **OSE and BI are Co-Developing BI 765063.** BI 765063 is a first-in-class humanized IgG4 monoclonal antibody targeting SIRPa, a component of the CD-47 pathway, which we've previously reviewed (here). The Company signed a global partnership with BI in April 2018 to develop BI 765063 in multiple cancer indications. The deal is worth up to $1.35 billion, assuming OSE reaches pre-specified development, commercialization, and sales milestones (prior note here).

Expected Upcoming Milestones

- Q4 2019 – Safety and Tolerability Data from Phase I study of OSE-127
- YE 2019-Q1 2020 – Topline Data from the Atalante-1 Phase III study evaluating *Tedopi* in NSCLC patients that have failed anti-PD1therapy
- H2 2020 – Data from TEDOPaM Phase II Study of *Tedopi* + *Opdivo* in pancreatic cancer patients

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Market Data

Price	$4.09
Market Cap (M)	$59
EV (M)	$27
Shares Outstanding (M)	14.4
Fully Diluted Shares (M)	15.0
Avg Daily Vol	7,549
52-week Range:	$3.05 - $5.02
Cash (M)*	$36.3
Net Cash/Share	$2.20
Annualized Cash Burn (M)	$21.1
Years of Cash Left	1.7
Debt (M)	$4.6

All relevant values covered at 1 Euro to 1.13 USD
**pro forma, includes an $11.3M milestone payment from Servier (private) and assumes €15M payment from Boeringher Ingelheim (private)*

Financials

FY Dec		2015A	2016A	2017A	2018A
EPS	H1	(0.34)	2.44	(0.53)	0.38
	H2	NA	NA	NA	NA

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FY	**(0.63)**	**1.77**	**(0.89)**	**0.43**

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. 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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