Morning Update

BRYAN, GARNIER & CO

19th October 2021

OSE IMMUNO

Healthcare
Biotech

BUY

TARGET PRICE	EUR17 (+71%)
SHARE PRICE	EUR9.97
EPS 3Y CAGR	NM

R&D day highlights the ongoing progress on the clinical and preclinical sides

KOL underlined favourable benefit/risk profile of Tedopi in NSCLC

Last week OSE Immunotherapeutics held an R&D day, highlighting its recent clinical and preclinical progress. On the clinical side, the presentation by Dr. Benjamin Besse, Head of the Cancer Medicine Department at Gustave Roussy, highlighted the final results from the phase III Atalante-1 study of Tedopi, recently presented at ESMO 2022 (see our note from September 23rd). As we discussed previously, in patients with secondary resistance to sequential CT-CPIs (population of interest or PoI), Tedopi improved mOS to 11.1 months compared to 7.5 months for chemotherapy (HR=0.59, p=0.02).

Dr. Besse provided an overview of the standard of care in NSCLC patients post CPI or CT-CPIs (without driver genomic alterations), underlining that SoC in most cases includes docetaxel as majority of the patients would receive CT previously. He highlighted that in Atalante-1, while DCR was similar between the study arms and ORR favoured SoC, Tedopi improved mOS and median post-progression survival in PoI as stand-alone therapy, with 60% of patients receiving subsequent treatment in Tedopi arm vs 42% in SoC. Dr. Besse stressed out a very favourable safety profile of Tedopi, with improved time to ECOG worsening: 8.6 vs 3.3 months (HR=0.45, p=0.0005), and concluded by discussing the evolving treatment landscape in NSCLC post CT-IO (Fig. 1). Among the presented studies, while the competition showed better ORR and PFS (based on early data), safety profile looks much more favourable for Tedopi. According to Dr. Besse, Tedopi had the most favourable benefit/risk ratio as VEGF TKIs and ADCs have shown worse toxicity profile.

As communicated previously, OSE is planning the discussions with the FDA and the EMA regarding the optimal regulatory path for Tedopi in NSCLC post CPI failure and we believe that another study in PoI setting will be required. As per Dr. Besse, the definition of secondary resistance could vary between patients that received only CPIs or CT-CPI together or sequential CT-CPI and we will be looking forward to hear the feedback from the regulators on the potential study design.

Combination studies for Tedopi

In our view, with clean safety profile and clinical activity as monotherapy, Tedopi is a promising combination partner. We remind that several combination studies are underway: i) the phase II Comb-TED study (n=105) in mNSCLC with secondary resistance to CT-CPI in combination with Opdivo or docetaxel vs docetaxel alone. The study will receive support from FoRT, Italian oncology foundation, and is expected to readout in 2024; ii) the phase II TEDOVA study (n=180) in ovarian cancer (1st or 2nd platinum sensitive relapse) as monotherapy or in combination with Keytruda vs best supportive care. This study is sponsored by ARCAGY-GINECO, French National Investigators Group for ovarian and breast cancer studies, and the anticipated completion is in 2025; iii) the phase II TEDOPaM study in pancreatic cancer in combination with FOLFIRI vs FOLFIRI alone, sponsored by GERCOR, French oncologists association, and is expected to redout in 2024.

(continued on next page)

Market Data	
Bloomberg / Reuters	OSE FP/OSE.PA
Market Cap.	EUR182m
E.V.	EUR172m
Free Float	0%
Avg. Daily volume (6m)	77.70
12m high / low	EUR15.0 / EUR6.3
Ytd Perf.	38.5%

EURM	12/20	12/21e	* 12/22e	* 12/23e
Sales	10.4	18.9	18.1	35.8
% Change		*81.4%*	*-4.3%*	*97.9%*
EBITDA	-19.0	-18.1	-10.8	1.8
% Change		*4.7%*	*40.2%*	*NS*
EBIT	-19.0	-18.1	-10.8	1.8
% Change		*4.7%*	*40.2%*	*NS*
Net Income	-16.6	-11.5	-6.2	5.3
% Change		*30.6%*	*45.8%*	*NS*
ROE	NM	NM	NM	NM

**Data have been modified by at least +/- 5% from last publication*

	12/20	12/21e	* 12/22e	* 12/23e
EV/Sales	16.8x	9.8x	10.6x	5.2x
EV/EBITDA	NS	NS	NS	102.0x
EV/EBIT	NS	NS	NS	102.0x
EPS	-1.06	-0.64	-0.35	0.29
% change		*40.0%*	*45.8%*	*NS*
P/E	NM	NM	NM	34.8x
Div Yield	NM	NM	NM	NM

Next Catalyst :

Initiation of the phase II study of BI 765063 - Q4 2021/Q1 2022

Last rating Change:

2020-1-13, Winning by DEALing with early-stage programs

Last FV Change:

2021-4-6, Positive 2021 outlook with anticipated advancements of the lead clinical programmes

Last Reports:

2021-9-23, Shaping up the pipeline of novel therapies in oncologic and autoimmune indications

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We remind that antigens, included in the Tedopi's design (such as MAGE2, MAGE3, CEA, HER2/neu, and P53 with a PADRE), are among broadly expressed tumour-associated antigens. For instance, ovarian cancers express MAGE-A2, MAGE-A3 and PRAME as well. Therefore, Tedopi could potentially be applied in different solid tumours. As we discussed previously, if positive, we believe that clinical updates from the combination studies could strengthen Tedopi's profile for potential in-licensing partner.

Figure 1: Competitive landscape in NSCLC post CT-CPIs

Company	MIRATI	Roche / EXELIXIS / IPSEN	MERCK / Eisai	gsk	AstraZeneca / Daiichi-Sankyo	SANOFI	OSE IMMUNOTHERAPEUTICS
Target	TKIs			Immunotherapy	ADC		Multi-epitope vacci
				TIM-3	TROP2	CEACAM5	
Study	MRTX-500	CONTACT-01	LEAP-008	COSTAR Lung	Tropion	CARMEN-LC03	ATALANTE-1
n	500	350	405	250	590	554	219
Therapy	Sitra + Opdivo vs. docetaxel	Cabo+Tecentriq vs. docetaxel	Lenvi + Keytruda vs. docetaxel	Cobolimab + Jemperli vs. docetaxel	datopotamab deruxtecan vs docetaxel	SAR408701 vs. docetaxel	Tedopi vs docetax
Primary endpoints	OS	OS	PFS and OS	OS and ORR	PFS and OS	PFS and OS	OS
Initiation	Q3 2019	Q3 2020	Q2 2019	Dec 2020	Q4 2020	Q1 2020	2017
Read-out	H2 2022 (interim)	2023	2023+	2024+	2022+	2022e	2021
Available data	n=68 Secondary resistance	n=30	n=21		n=175 Dose levels: 4, 6, 8 mg/kg		n=118 Secondary resistnace
mOS	15 mo						11.5 mo
mPFS	5.7 mo		5.9 mo		4.3 mo, 8.2 mo, 5.4 mo		2.7 mo
ORR	18%	27%	33%		23%, 21%, 25%		8%
CR	3%		5%		0%, 0%, 1%		
mDOR	12.8	5.7 mo	10.9 mo		NE, 10.5 mo, 9.4 mo		
Gr3/4 TRAEs	66%		67%		10%, 16%, 34%		11%
Discontinuation rate	22%		13%-15%		16%, 14%, 24% ILD		0%

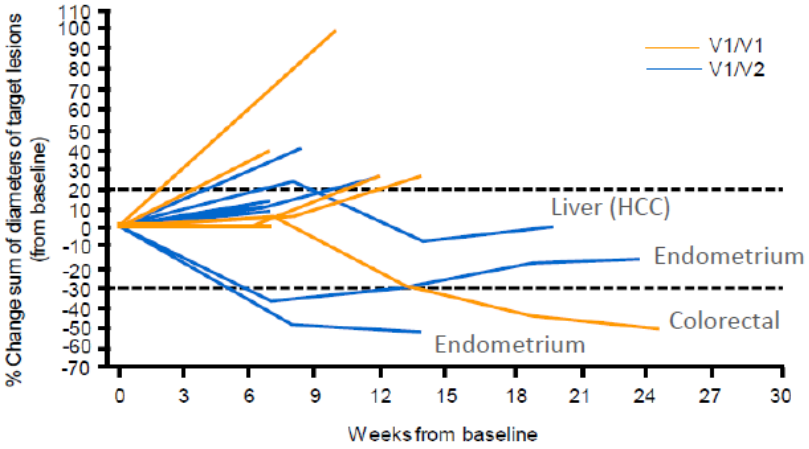
Source: OSE presentation and Bryan Garnier Research

Highlighting advantages of targeting SIRPα

Another clinical presentation included discussion on OSE's anti-SIRPα therapy, out-licenced to Boehringer Ingelheim, BI 765063. The results from the phase I dose-escalation part of the study of BI 765063 in combination with anti-PD-1 from BI, ezabenlimab, in solid tumours were presented at ESMO 2021 as well (see our note from September 17th). We remind that out of 16 evaluable patients, who received 2-5 prior lines of systemic therapy, tree had confirmed PRs (although one PR was not sustained): two patients with endometrial cancer and one with CRC. Two patients with known tumour characteristic had MSS and PD-L1+ status. Additionally, one patient with HCC achieved stable disease (Fig. 2). We also note that while numbers are limited there was no notable difference between responses in V1/V1 and V1/V2 patients, suggesting that it could be sufficient to target only V1 SIRPα even in heterozygous patients. Although dose-expansion part of the phase I study is expected to include only V1/V1 patients, V1/V2 population could be included in the following phase II. We remind that according to company's estimates, 43% of the study population carried V1/V1 phenotype and 45% - V1/V2, leading to potential total coverage of 88% of target population.

While early, considering MSS status and number of prior lines of therapy, we believe that the combination of BI 765063 and ezabenlimab showed encouraging clinical activity. We note that the competitive asset, an anti-CD47 magrolimab from Forty Seven (now Gilead), did not impress in r/rCRC (although in combination with cetuximab in cetuximab-refractory setting): in the combined phase I+II study, only two out of 30 evaluable KRASwt CRC patients had confirmed PRs for 7.0 and 12.5 months, with mPFS and mOS of 3.6 and 10.1 months, respectively. In our view, BI 765063 and ezabenlimab combo could potentially prove to be a more effective combination in CRC, as well as endometrial cancer. While PD-L1 status does not directly correlate with responses to anti-PD-(L)1 in MSS type of disease (as response to CPI in this setting is very poor in general), we will be watching the data from the dose-expansion part of the phase I to better understand if PD-L1 status could serve as a biomarker for response to this combination.

Figure 2: Clinical activity of BI 765063 and ezabenlimab combination



Source: OSE's R&D day presentation

We also previously discussed that beyond improved safety profile, one of the advantages of selective SIRPα-targeting (vs CD47) is the avoidance of SIRPγ inhibition as CD47 could interact with this receptor as well (see our note from January, 2020). Unlike SIRPα, SIRPγ is expressed on T-cells and might be important for their migration to the tumor site. OSE's CSO Dr. Nicolas Poirier highlighted the potential role of SIRPγ in T cell proliferation during PD-1/L1 blockade as it was one of the few upregulated genes that differentiated responders vs non-responders. These conclusions are based on the melanoma, renal and gastric cancers samples, which showed that SIRPγ+ T cells were enriched in anti-PD-1 responders. According to Dr. Poirier, the preclinical models would not be able to show this important feature of SIRPγ as its expression is specific to primates. Overall, the selective inhibition of SIRPα could bypass a potential 'off-target' inhibition of SIRPγ, potentially representing a better combination partner for CPIs.

Preclinical pipeline focus

Among myeloid checkpoint inhibitors, like SIRPα/CD47 pathway, OSE also highlighted a novel preclinical asset, which targets CLEC-1 pathway and could be moved into the clinic in H2 2023. Under normal conditions CLEC-1, a C-type lectin receptor that is expressed on dendritic cells and macrophages, helps to prevent immune cell mediated tissue damage by suppressing the activation of myeloid cells. Albeit, in the tumor context CLEC-1 signalling helps to evade the immune response. Notably, expression of the CLEC-1 ligand surges in 'stressed' tumour cells and inhibits tumour phagocytosis and cross-priming to T cells. The preclinical data, presented by the company earlier at AACR 2020 meeting showed that targeting CLEC-1 signalling with antagonistic antibody synergized with chemotherapy and induced complete response in 37% of mice versus 0% in chemotherapy group (context of stressed tumour cells). CLEC-1 antagonist also showed synergy with tumour-targeting antibodies, such as rituximab, cetuximab and trastuzumab in *in vitro* studies. Thus, we believe that targeting CLEC-1 could represent a novel and promising therapeutic strategy in multiple tumor types.

Among the preclinical pipeline, the company also highlighted its bispecific BiCKI platform, which is based on the backbone of in-house anti-PD-1 antibody (OSE-279). The first clinical asset is expected to target PD-1 and simultaneously induce IL-7 signalling. We remind that the preclinical studies of OSE-279 showed full inhibition of PD-1 signalling and the ability to suppress tumor growth (see our note from January 2020). As per IL-7, it binds to the IL-7 receptor (IL-7Rα) on the surface of T cells and triggers their proliferation and long-term survival. Importantly, IL-7 induces naïve and memory T cells proliferation without expansion of immuno-suppressive T regs (like earlier IL-2 assets). Dr. Poirier also discussed the academic paper published in Nature in 2021, which showed that while TILs have lower IL-7R expression those are exhausted apoptotic populations and anti-PD-1 non-response specifically had lower IL-7R expression. The authors suggested that because IL-7 signalling is a requisite for maintenance of T cell homeostasis and long-lived memory, targeting the IL-7 pathway could enhance response to CPIs, which bodes well for OSE's first BiCKI asset. OSE's preclinical studies have shown that BiCKI-IL-7 could prevent T-cells exhaustion and restore TILs reactivation. BiCKI-IL-7 is currently expected to reach the clinical phase in H2 2022.

We also note that the preclinical data on both assets will be presented at SITC 2021, which will take place on November 12-14, and the abstracts are expected to be released on November 9th.

Overall, we highlight the expanding OSE's pipeline and the ongoing progress on both clinical and preclinical sides. Considering OSE's track-record in securing early partnership agreements, we believe that the company has all cards in hands to reproduce previous success in the future as well as to continue the progress on clinical side.

Morning Update

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OSE IMMUNO

BUY	
Target price	EUR17 (+71%)
Share price	EUR9.97
Market Cap.	EUR182m
EPS 3Y CAGR	NM

Fiscal year end 31/12	2019	2020	* 2021e	* 2022e	* 2023e
Financial Summary					
EPS (EUR)	-0.31	-1.06	-0.64	-0.35	0.29
Restated EPS (EUR)	-0.31	-1.06	-0.64	-0.35	0.29
% change	-184.5%	-239.9%	-40.0%	-45.8%	-
Net dividend (EUR)	0.00	0.00	0.00	0.00	0.00
Average yearly Price	3.7	-	-	-	-
Avg. Number of shares, diluted (m)	14.8	15.6	18.0	18.0	18.0
Historical Entreprise value (EURm)	8.61	-	-	-	-
Valuation (x)					
EV/Sales	0.3x	-	9.65x	10.38x	5.07x
EV/EBITDA	-5.9x	-	NM	NM	99.87x
EV/EBIT	-5.9x	-	NM	NM	99.87x
P/E	-11.9x	-	NM	NM	34.12x
Net dividend yield (%)	0.0%	-	NM	NM	NM
Profit & Loss Account (EURm)					
Revenues	26.0	10.4	18.9	18.1	35.8
Change (%)	6%	-60%	81%	-4%	98%
R&D	-21.6	-22.4	-27.0	-22.0	-27.0
Adjusted EBITDA	-1.4	-19.0	-18.1	-10.8	1.8
EBIT	-1.4	-19.0	-18.1	-10.8	1.8
Change (%)	-1.3	-12.1	0.0	-0.4	-
Financial results	0.0	-0.3	-0.2	-0.4	-0.4
Pre-Tax profits	-1.5	-19.2	-18.3	-11.2	1.4
Exceptionals	0.0	0.0	0.0	0.0	0.0
Tax	-3.2	2.7	6.8	5.0	3.8
Profits from associates	0.0	0.0	0.0	0.0	0.0
Minority interests	0.0	0.0	0.0	0.0	0.0
Net profit	-4.6	-16.6	-11.5	-6.2	5.3
Restated net profit	-4.6	-16.6	-11.5	-6.2	5.3
Change (%)	-185%	-257%	-31%	-46%	-
Cash Flow Statement (EURm)					
Operating cash flows	-5	-17	-11	-6	5
Change in working capital	9	-3	0	0	0
Capex, net	5.27	-0.02	0.88	0.88	0.88
Free Cash flow	9	-19	-11	-5	6
Financial investments, net	2.4	-0.5	0.0	0.0	0.0
Dividends	0	0	0	0	0
Capital increase	6	24	10	10	0
Other	-1	-1	0	0	0
Net debt (+)/cash (-)	-15	-11	0	5	-1
Balance Sheet (EURm)					
Tangible fixed assets	1.0	0.9	0.9	0.9	0.9
Intangibles assets	52.6	52.6	51.7	50.8	50.0
Cash & equivalents	25.8	29.4	28.5	32.9	38.8
current assets	7.2	10.5	10.5	10.5	10.5
Other assets	2.3	3.6	3.6	3.6	3.6
Total assets	88.9	97.0	95.2	98.7	103.8
L & ST Debt	11.2	18.9	28.7	38.4	38.2
Provisions	0.4	0.5	0.5	0.5	0.5
Others liabilities	16.8	13.5	13.5	13.5	13.5
Minority interests	0.0	0.0	0.0	0.0	0.0
Shareholders' funds	58.5	61.4	49.9	43.6	48.9
Total Liabilities	30.4	35.6	44.8	54.5	54.3
Ratios					
Gross margin	100.0%	100.0%	100.0%	100.0%	100.0%
EBITDA margin	-5.6%	-182.3%	-95.7%	-59.8%	5.1%
Operating margin	-5.6%	-182.3%	-95.7%	-59.8%	5.1%
Tax rate	-	-	-	-	-
Net margin	-17.9%	-158.9%	-60.8%	-34.5%	14.7%
Dividend payout	0.0%	0.0%	0.0%	0.0%	0.0%

Source: Company Data; Bryan, Garnier & Co ests.

BRYAN, GARNIER & CO

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Stock rating

CONVICTION BUY	The highest possible rating, based on a very strong conviction in the mid/long-term outlook and strategic choices made by a company, and should therefore be reflected in the extent of upside in the associated target price. There is no reason to limit the number of CONVICTION BUY ratings, however they must also reflect some kind of preference in relative terms within a sector.
BUY	This rating should traditionally be applied to companies for which we expect a positive absolute share price performance over a 6 to 12 month period. The opinion is based not only on the TP (which represents theoretical upside relative to the current share price over a 12-month period) but also takes into consideration a number of other factors that may include a SWOT analysis, momentum, technical aspects or the sector backdrop.
NEUTRAL	This rating is the equivalent of a recommendation not to trade in a stock in the short term, either as a buyer or a seller, for many potential reasons. The view is intended to be temporary since it has been proven that few stocks actually remain within a narrow -5%/+5% range over a long period of time. The rating is particularly valid in exceptional market conditions. Our intention is to limit the total number of NEUTRAL ratings to 20%.
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CONVICTION SELL	This is the lowest possible rating reflecting a strong disagreement with the main strategic choices made by a company, pointing to the risk of de-rating and value destruction and which is obviously also reflected in downside potential between the share price and the target price.
NOT RATED	Covered stocks may be "Not rated" when we view them as being interesting for one or several strategic themes in our universe, but consider that we do not have a general enough perspective or overall assessment of them to be able to issue a rating. As such, our comments are limited to topics where we believe we can add value. More specifically, quarterly earnings will not be commented on per se.
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TARGET PRICE	As of September 2020, we are moving our historical FV (Fair Value) system to share our views on the theoretical valuation of a company, to a TP (Target Price) system. The main reason behind this change is to provide flexibility in reflecting the different scenarios and assumptions we make for each investment case. FV was the theoretical valuation of a company NOW. TP will be the theoretical value of a company over a standard 12-month period. With this new system, it will therefore be possible to include many more scenarios, to make more accurate and precise assumptions and to some extent, to project ourselves at the right time for the purpose of the investment case. With TP instead of FV, we should also be more aligned with our ratings, which is always better for a good global understanding of our opinions.

Distribution of stock ratings

Conviction BUY ratings 6.5% BUY ratings 61.2% NEUTRAL ratings 18% SELL ratings 14.4% Conviction SELL ratings 0%

ESG

E S G	GREEN	The highest possible rating, reflecting a positive overall assessment of the company re pre-defined criteria.
	ORANGE	The rating means that we have identified at least one topic which deserves attention and would require corrective measures.
	RED	This is a red flag. The rating says that there is at least one topic identified that is simply not acceptable at present state.
	GREY	Not rated, mainly because of insufficient data.

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