EDISON

OSE Immunotherapeutics

Clinical update

Timely FR104/VEL-101 update with Phase II plans

Pharma and biotech

OSE Immunotherapeutics (OSE) has shared a positive update on the FIRsT clinical trial assessing FR104/VEL-101 (an anti-CD28 monoclonal antibody) as a maintenance therapy for kidney transplant patients. Long-term maintenance therapy in kidney transplant patients remains an ongoing medical need that has seen little progression in the last 20 years. Although OSE is in the early stages of clinical development, we believe there could be a significant opportunity. Encouragingly, the results show no safety concerns with FR104/VEL-101 treatment (seven patients for 12 months post-transplantation, and one ongoing at four months) and no cases of acute rejection, both of which are key objectives for this Phase I/II trial. While the FIRsT study involves a relatively small group size (eight evaluable patients), we believe the update is encouraging, and note that Veloxis Pharmaceuticals (OSE's partner for this programme) is already preparing for a subsequent Phase II trial involving a larger patient population. We expect full results from the FIRsT study after all patients have completed the 12-month treatment protocol, most likely in H224.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/21	26.3	(17.2)	(0.95)	0.0	N/A	N/A
12/22	18.3	(18.0)	(0.97)	0.0	N/A	N/A
12/23e	2.7	(26.2)	(1.34)	0.0	N/A	N/A
12/24e	15.0	(21.8)	(0.98)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

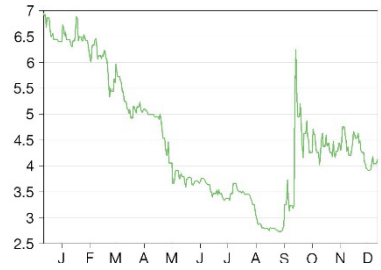
The FIRsT study is being sponsored and conducted by the University Hospital of Nantes. This Phase I/II trial is investigating FR104/VEL-101 in kidney transplant patients, assessing safety, tolerability and pharmacokinetics, as well as its potential efficacy in acute rejection prophylaxis and renal function. Patients are monitored for one year, and tacrolimus (a calcineurin inhibitor used to reduce the risk of organ rejection) is discontinued six months post-transplantation. Ten patients have been enrolled, all of whom were deemed to be at low risk of rejection, as per the study protocol, but two patients were not transplanted for technical reasons. While one patient is still undergoing the treatment protocol (currently at four months), this interim analysis included 12-month data on the remaining seven patients.

Among the evaluable patients, there have been no safety concerns reported up to one year of follow-up. While there have been some adverse events, these were considered typical for patients undergoing kidney transplantations. A key objective is to replace calcineurin inhibitors (standard of care after such procedures) with potentially safer alternative immunosuppressive treatments, as otherwise long-term exposure may lead to adverse events, nephrotoxicity and/or allograft rejection. Importantly, the interim analysis for the FIRsT study showed no acute rejection with FR104/VEL-101, even after discontinuation of tacrolimus. We highlight that long-term management of maintenance immunosuppression in kidney transplant patients remains an ongoing medical need. Recent US congressional activities also highlight the increasing need to manage transplant maintenance including end-stage renal disease. Therefore, although in the early stages, we believe there is significant opportunity for OSE and Veloxis Pharmaceuticals in this space.

12 December 2023

Price	**€4.03**
Market cap	**€87m**
	€0.94/US$
Pro-forma net debt (€m) at 30 June 2023 (including September equity raise)	8.2
Shares in issue	21.7m
Free float	65%
Code	OSE
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



Business description

OSE Immunotherapeutics is based in Nantes and Paris in France and is listed on the Euronext Paris exchange. It is developing immunotherapies for the treatment of solid tumours and autoimmune diseases and has established several partnerships with large pharma companies.

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