EDISON

Basilea Pharmaceutica

Clinical data updated

New supportive data from ERADICATE

Pharma/biotech

Basilea Pharmaceutica has presented detailed data from the Phase III ERADICATE study of Zevtera (ceftobiprole) in the treatment of *Staphylococcus aureus* bacteraemia (SAB). In this, Zevtera demonstrated an overall success rate of 77.9% (77.8% for daptomycin), a microbiological eradication rate of 82.0% (77.3% for daptomycin), an all-cause mortality rate of 9.0% (9.1% for daptomycin) and a new SAB complications rate of 5.8% (5.6% for daptomycin) at 70 days post-randomisation in the modified intent-to-treat population. Additionally, the median time to bloodstream clearance for methicillin susceptible *Staphylococcus aureus* (MSSA) was three days with Zevtera (four days with daptomycin), and five days for MRSA for Zevtera and daptomycin. These secondary outcomes add to the previous reporting that ERADICATE met the primary endpoint of non-inferiority versus the comparator arm. We see these new data as supportive of Zevtera's utility in treating serious bacterial infections and as an important result for the company. Our valuation of Basilea Pharmaceutica is unchanged at CHF903.5m or CHF76.3/share.

Year end	Revenue (CHFm)	PBT* (CHFm)	EPS* (CHFc)	DPS (p)	P/E (x)	Yield (%)
12/20	127.6	(29.6)	(288.5)	0.0	N/A	N/A
12/21	148.1	(6.6)	(56.9)	0.0	N/A	N/A
12/22e	121.0	(15.3)	(129.4)	0.0	N/A	N/A
12/23e	128.8	6.4	47.0	0.0	94.0	N/A

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

Zevtera is a broad-spectrum antibiotic for the treatment of drug-resistant infections, including methicillin-resistant *Staphylococcus aureus* and Gram-negative bacterial infections, including Pseudomonas. The Phase III ERADICATE study protocol enrolled 390 patients with SAB caused by MRSA or MRSS, who were randomised into either the active arm (ceftobiprole iv infusion) or the comparator arm (daptomycin with or without aztreonam for Gram-negative infections). We note the primary endpoint of ERADICATE was non-inferiority (15% non-inferiority margin) versus daptomycin (+/- aztreonam), hence any conclusion concerning Zevtera's superiority to the control arm cannot be drawn.

Considering the halting of main competitor Exebacase's Phase III DISRUPT trial for futility in July, we view these newly reported data as encouraging support for Zevtera's potential commercial impact. With the results from ERADICATE in hand management is now preparing the data required for a new drug application (NDA) submission to the FDA, which we expect the company will submit around year-end 2022. As the ERADICATE and TARGET trial designs were agreed with the FDA under a special protocol assessment, we do not foresee any problems. We maintain that a US launch date of late-FY23 for ceftobiprole with a focus on SAB and acute bacterial skin and skin structure infections is feasible, based on a timely NDA submission at the end of 2022 and we expect the company will look to partner before approval.

25 October 2022

Price	**CHF44.2**
Market cap	**CHF575m**

Net debt (CHFm) at 30 June 2022	71.2
Shares in issue (includes 1.15m shares in treasury)	13.0m
Free float	90%
Code	BSLN
Primary exchange	SIX
Secondary exchange	N/A

Share price performance

Business description

Basilea is focused on treating infectious diseases. Its marketed products are Cresemba (an antifungal) and Zevtera (an anti-MRSA broad-spectrum antibiotic). The company now plans to file for US approval for Zevtera.

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