EDISON

Diurnal Group

Clinical update

First patient dosed in the US CONnECT study

Pharma & biotech

Diurnal has dosed the first patient in its pivotal Phase III CONnECT clinical trial assessing DNL-0200/Efmody in adults with congenital adrenal hyperplasia (CAH) for the US and Japanese markets, marking a key step in the asset's clinical progression. The year-long trial is the first blinded study in CAH, according to management. Headline data are expected in 2024 and are material to Efmody's prospects in United States. We also believe positive results from this study could potentially create an uplift in sales for Efmody in Europe, where the market sentiment has been affected by the recent SMC decision.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
06/20	6.3	(5.1)	(4.1)	0.0	N/A	N/A
06/21	4.4	(11.1)	(7.0)	0.0	N/A	N/A

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

Diurnal has announced that the first patient has been dosed in its Phase III clinical study for Efmody (DNL-0200) in CAH (CONnECT) for the US and Japanese markets. The trial is expected to enrol up to 150 patients with CAH, who will be treated for 52 weeks. The company anticipates completing patient enrolment in the next 12 months, with headline data likely to be announced in H224.

As a reminder, the CONnECT study is a Phase III randomised, double-blind, active-controlled clinical trial that will mainly assess the efficacy, safety and tolerability of modified-release hydrocortisone in comparison with immediate-release hydrocortisone therapy in adults with CAH. This study is being conducted under the special protocol assessment, which includes an agreement with FDA that the trial design 'adequately addresses objectives that would support the regulatory submission for drug approval'.

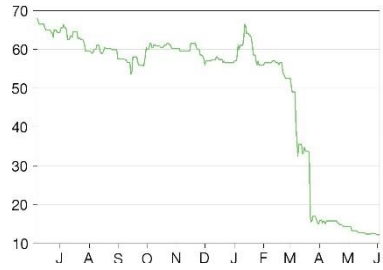
The study results will be accepted by both the US and Japanese regulators. The Japanese Pharmaceutical and Medical Devices Agency has agreed to accept the study on the condition that Japanese patients be included. As a result, the trials will be conducted at four sites, in the US, Japan, France and Turkey. The French and Turkish sites have been included to maximise patient accrual rates, as stated by the company.

Efmody is already approved in Europe for CAH, but the recent SMC decision to not recommend it for automatic reimbursement in NHS Scotland has proved to be a headwind for Efmody's UK (and potentially some other European markets) roll-out plan. The ongoing US study is larger than the completed EU clinical study (122 patients). A positive outcome could have an important read-across for clinical stakeholders and recommendation committees in Europe. Additionally, with the United States being an important market for CAH, if achieved we expect FDA approval to potentially create a strong base for future Efmody clinical trials for the larger adrenal insufficiency indication.

6 June 2022

Price	**12.3p**
Market cap	**£21m**
Net cash (£m) at 31 December 2021	24.4
Shares in issue	169.3m
Free float	68.1%
Code	DNL
Primary exchange	LSE
Secondary exchange	N/A

Share price performance



Business description

Diurnal Group is a specialty pharma company developing new formulations of hormone-based products for the treatment of endocrine disorders. Alkindi is marketed for paediatric adrenal insufficiency in the US and EU. Efmody is approved for the treatment of congenital adrenal hyperplasia in the EU and UK.

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