Molecure

Clinical trials initiated for second asset

As presented at its R&D day in December 2022, Molecure has now initiated the clinical trial for its second candidate, OATD-02. This Phase I trial is an open-label, multi-centre, first-in-human, dose-escalation study. The company will target cancers where immune checkpoint inhibitors (ICIs) have had limited success, an area where we believe OATD-02/ICI combinations could have an impact. In our view, this milestone supports Molecure's development strategy and we expect an update on this trial in H223. The company also has pre-clinical animal model data for OATD-01 for the treatment of sarcoidosis, which suggests potential use in non-alcoholic steatohepatitis, a fibrotic disease with unmet need.

OATD-02 is being developed as a potential new oral drug for the treatment of a range of solid tumours. It is the first and only dual-acting arginase inhibitor addressing both tumour immunity and metabolism. Arginases 1 and 2 are validated therapeutic targets associated with a variety of tumour types and OATD-02 is designed to help restore antitumour immune responses by overcoming the immunosuppressive tumour environment. Following approval from the Polish authorities in November 2022, Molecure has now initiated its Phase I trial for OATD-02 as a monotherapy.

This Phase I trial will primarily focus on evaluating the safety and tolerability of the drug. Additional objectives include assessing preliminary efficacy (response and survival), measuring pharmacokinetic/pharmacodynamic biomarker data and establishing a maximum tolerated dose. A Bayesian optimal interval design is being used; management believes this may accelerate the identification of the recommended Phase II dose. The study is based across three sites in Poland and aims to recruit c 40 patients with advanced and/or metastatic solid tumours. Management intends to target indications where ICIs have low response rates, namely, colorectal cancer, platinum-resistant ovarian cancer, pancreatic cancer, or renal cell carcinoma.

We view the first patient dosing in this trial as a key milestone for Molecure, with OATD-02 being the second candidate from the company's proprietary pipeline to enter clinical development. Management expects to see the initial data from this study in H223, which, if positive, would support the further clinical progression of the asset. We also expect that results from this trial will inform the design of further Phase I/II trials in combination with ICIs.

Historical figures

Year end	Revenue (PLNm)	EBIT (PLNm)	EPS* (PLN)	DPS (PLN)	P/E (x)	Yield (%)
12/20	124.9	73.7	4.64	0.0	4.5	N/A
12/21	1.46	(13.8)	(0.98)	0.0	N/A	N/A

Source: Company accounts. Note: *Diluted EPS

Pharma and biotech

10 March 2023

Price	PLN21.0
Market cap	PLN295m

Share price graph

Share details

Code	MOC
Listing	Warsaw Stock Exchange
Shares in issue	14.06m
Cash (PLNm) at 30 September 2022	80.7

Business description

Molecure is a clinical-stage biotechnology company. It uses its medicinal chemistry and biology capabilities to discover and develop first-in-class small-molecule drug candidates that directly modulate underexplored protein targets and the function of RNA to treat multiple incurable diseases.

Bull

- Two assets to enter clinical development by end-FY23.
- OATD-01 has potential for disease-modifying action in interstitial lung disease.
- Pipeline supported by pre-clinical assets and technology platform.

Bear

- Delays or disruptions to timelines could affect management's estimated cash runway.
- Unvalidated mechanisms of action increase development risk.
- Additional funding needed to complete Phase II development.

Analysts

Soo Romanoff +44 (0)20 3077 5700

Arron Aatkar +44 (0)20 3077 5700

healthcare@edisongroup.com

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London | New York | Frankfurt
20 Red Lion Street
London, WC1R 4PS
United Kingdom