Kiadis Pharma (KDS.AS)

Kiadis Remains on Track for CHMP Decision Regarding ATIR101 in Q4 2018

Kiadis Pharmaceuticals (AMS: KDS) recently provided an update on operational and financial activities. The Company is on track to receive an opinion from the Committee for Medical Products for Human Use (CHMP) regarding the Marketing Authorization Application (MAA) of ATIR101, the Company's lead candidate, in Q4, which represents the next catalyst for Kiadis. As a reminder, the Company is seeking approval for ATIR101 in hematological malignancies in Europe. Kiadis also announced a protocol amendment to an ongoing Phase III study evaluating ATIR101, compared to post-transplant cyclophosphamide (PT-Cy) in patients with acute hematological malignancies. The study was modified to increase the number of patients from 195 to 250 in order to provide sufficient powering. Kiadis ended the first 6 months of 2018 with €41.7 million ($48.8 million) in cash and cash equivalents.

- **ATIR101 on Track to Receive EMA CHMP Opinion in Q4.** As a reminder, Kiadis submitted responses to the Day 120 List of Questions in March of this year, which was subsequently followed up with a Day 180 List of Questions in May. The Company submitted the responses to the list of questions in August. Under EMA pre-authorization the CHMP has up to 210 active days to evaluate the MAA. Given that Kiadis submitted responses to the Day 180 questions in August, a decision may come sometime in Q4 2018.
- **Protocol Amendment to CR-AIR-009; Interim Analysis Now Expected in H2 2020.** Kiadis gave an update with respect to its ongoing Phase III CR-AIR-009 study. This is a randomized controlled open-label trial evaluating ATIR101 compared to PT-Cy in patients with acute hematological malignancies for potential registration in the US. ATIR101 has Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA, which is similar to breakthrough designation for drug candidates, in that RMAT designated products may be eligible for priority review, thereby accelerating approval of the therapy. So far, a total of 16 patients have been enrolled across 14 open clinical sites. The Company amended the study to include 250 patients, an increase from the 195 patients originally planned to be enrolled in the study. The addition of more subjects will increase the power of the study to 80%, in order to detect a 16% graft-versus host diseases-free survival and relapse-free survival (GRFS) difference. Recall GFRS is the primary endpoint of the study. Kiadis now expects to report interim results during the second half of 2020, pushed back from the previous H1 2019 guidance.

Expected Upcoming Milestones

- Q4 2018 – Receive EMA CHMP decision.
- Q1 2019 – Potential approval (conditional or full) for ATIR101 in the EU.
- H2 2019 – Potential initial commercial launch of ATIR in first EU countries.
- H2 2019 – Initiate ATIR101 as adjunctive to PT-Cy.
- 2019 – Potential commercialization of ATIR101 in the EU.
- H1 2020 – Potential reimbursement and commercial roll out across EU countries.
- H2 2020 – Potential interim read out Phase 3 (at 2/3 of GRFS events).

Analysts

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Market Data

Price	$11.10
Market Cap (M)	$223
EV (M)	$199
Shares Outstanding (M)	20.1
Fully Diluted Shares (M)	21.3
Avg Daily Vol	69,708
52-week Range:	$5.93 - $16.12
Cash (M)*	$45.0
Net Cash/Share	$1.01
Annualized Cash Burn (M)	$23.0
Years of Cash Left	2.0
Debt (M)	$24.0

All relevant values converted at 1 Euro to 1.16 USD

**pro forma*

Financials

FY Dec		2015A	2016A	2017A	2018A
EPS	H1	(0.95)	(0.51)	(0.63)	(0.87)
	H2	NA	NA	NA	NA
	FY	(1.45)	(1.15)	(1.40)	NA

For analyst certification and disclosures please see page 3

- **Half Year 2018 Financial Results**. Kiadis Pharmaceuticals announced financial results for the first half of 2018. General and administrative expenses were €3.4 million ($3.98 million), compared to €2.3 million ($2.7 million) during the same period in 2017. Research and development expenses were €7.7 million ($9.0 million) compared to €5.9 million ($7.0 million) during the first six months in 2017. The Company reported a net loss for the quarter of €14.1 million ($16.5 million), or €0.74 ($0.87) per share, compared to €8.5 million ($10.1 million), or €0.61 ($0.73) per share during the same period 2017. As of June 30th, the Company had €41.7 million ($48.8 million) in cash and cash equivalents.

Risk to Investment

We consider an investment in Kiadis to be a high-risk investment. Kiadis is a developmental stage company with no history of taking a treatment to market, and currently has no FDA or EMA approved products in its portfolio. The Company's products in development may fail in clinical trials or fail to be approved by the FDA or other regulatory agencies. Furthermore, early indications of efficacy do not necessarily translate into positive late-stage results. As with any company, Kiadis may be unable to obtain sufficient capital to fund planned development programs. Regulatory approval to market and sell a drug does not guarantee that the drug will penetrate the market, and sales may not meet the expectations of investors.

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