Kiadis Pharma (KDS.AS)

Kiadis Reports 1-Year Follow-up of Single Dose Patients in the CR-AIR-008 Study

Earlier today, Kiadis Pharmaceuticals (AMS: KDS) gave a 1-year update on 5 patients from its CR-AIR-008 Phase II study evaluating ATIR101 in adults with acute blood malignancies who have received a half-matched hematopoietic stem cell transplant (HSCT). Results from this trial were consistent with a previous study. ATIR101 is a donor lymphocyte infusion that is given after an allogeneic HSCT (allo-HSCT) to prevent GvHD and mitigate the risk of disease relapse and infection. Other competitors in this space include Bellicum's (NasdaqGM: BLCM) BPX-501 and MolMed's (BIT:MLMD.MI) *Zalmoxis*. BPX-501 was placed on clinical hold yesterday by the FDA after 3 reported cases of encephalopathy. To our knowledge, there have been no reported cases of encephalopathy with Kiadis' therapy. A Marketing Authorization Application (MAA) for the approval of ATIR101 in Europe has been submitted and accepted for review by the EMA. A regulatory decision from the agency is expected during the second half of 2018 and represents the next inflection point for Kiadis.

- **One Year Follow up of Patients is in Line with Previous Data.** Kiadis reported the one year follow up of 5 patients and dosing of the last patient in its CR-AIR-008 Phase II study. Based on the update, 5 of 9 patients treated with ATIR101 in this study experienced clinical benefits that were consistent with the previous CR-AIR-007 Phase II trial in the same indication. This announcement further validates the results of the CR-AIR-007 trial, and support the already submitted marketing authorization application (MAA) for the therapy in the EU.
- **Competing Ex Vivo Cell Therapy Put on Clinical Hold for Encephalopathy.** Bellicum's BPX-501 was placed on clinical hold by the FDA in the US after 3 reported cases of encephalopathy, highlighting a possible complication that may impact its use if approved. One patient died as a result of encephalopathy, which was confirmed with a brain biopsy. This particular patient had a history of immunodeficiency and concurrent virus infections, which has been linked to encephalopathy after an HSCT. After the patient death, two subjects in the study were categorized as having treatment related encephalopathy, which was ultimately resolved. The encephalopathy in these patients was deemed not treatment related prior to the patient death occurring. We note that an analysis of 405 pediatric patients who received an allogeneic HSCT found that 6.4% (26/405) developed encephalopathy. BPX-501 has been dosed in more than 240 patients and the company's registrational BP-004 trial will continue as planned in the EU. Based on this, it is possible that the clinical hold will eventually be lifted in the US.

Expected Upcoming Milestones

- H2 2018 – Potential approval (conditional or full) for ATIR101 in the EU.
- 2018 – Initiate ATIR101 as adjunctive to PT-Cy and/or other T cell depleted HSCT.
- 2019 – Potential commercialization of ATIR101 in the EU.

Analysts

David Sherman, Ph.D. (AC)
(212) 915-2570
dsherman@lifescicapital.com

Market Data

Price	**$16.62**
Market Cap (M)	**$281**
EV (M)	**$270**
Shares Outstanding (M)	**16.9**
Fully Diluted Shares (M)*	**18.1**
Avg Daily Vol	**205,907**
52-week Range:	**$6.33 - $16.72**
Cash (M)	**$48.0**
Net Cash/Share	**$0.67**
Annualized Cash Burn (M)	**$18.0**
Years of Cash Left	**2.7**
Debt (M)	**$37.0**

All relevant values converted at 1 Euro to 1.24 USD
Cash and debt are pro forma
**Does not take into account the exercise of warrants on 10/10/17.*

Financials

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

For analyst certification and disclosures please see page 3

Noninfectious causes of encephalopathy have also been identified, including treatment with cyclosporine, tacrolimus, and ganciclovir. The latter is particularly interesting given that ganciclovir is critical in the activation of MolMed's *Zalmoxis*, an *ex vivo* cell therapy, to reduce GvHD in patients with hematological malignancies after a haploidentical HSCT. MolMed has not reported encephalopathies related to treatment. We also note that Kiadis' ATIR101 does not require the use of ganciclovir or genetic manipulation, and to our knowledge, no cases of encephalopathy have been reported as a result of the treatment. Finally, Kiadis is addressing adults with acute malignancies, while the aforementioned therapies are targeting pediatric patients with inherited blood disorders and blood malignancies.

- **Phase II CR-AIR-008 Trial Design.** This was an open-label Phase II trial to evaluate whether the effects of ATIR101 could be extended by adding a second dose of ATIR101. A total of 15 patients were enrolled and 6 received 2 doses of ATIR101. 2 of the 6 patients treated with a second dose of ATIR101 reported grade III/IV GvHD. As a result, the Company terminated administration of a second dose of ATIR. The remaining 9 patients received one dose of ATIR101 as a donor lymphocyte infusion 30 days after a HSCT. The primary endpoint of the study was the incidence of acute graft versus host disease (GvHD) and secondary endpoints included incidence of chronic GvHD, overall survival (OS), and GvHD-free, relapse-free survival (GRFS).

Risk to Invesment

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.

Analyst Certification

The research analyst denoted by an "AC" on the cover of this report certifies (or, where multiple research analysts are primarily responsible for this report, the research analyst denoted by an "AC" on the cover or within the document individually certifies), with respect to each security or subject company that the research analyst covers in this research, that: (1) all of the views expressed in this report accurately reflect his or her personal views about any and all of the subject securities or subject companies, and (2) no part of any of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst(s) in this report.

DISCLOSURES

This research contains the views, opinions and recommendations of LifeSci Capital, LLC ("LSC") research analysts. LSC (or an affiliate) has received compensation from the subject company for producing this research report. Additionally, LSC expects to receive or intends to seek compensation for investment banking services from the subject company in the next three months. LSC (or an affiliate) has also provided non-investment banking securities-related services, non-securities services, and other products or services other than investment banking services to the subject company and received compensation for such services within the past 12 months. LSC does not make a market in the securities of the subject company.

Neither the research analyst(s), a member of the research analyst's household, nor any individual directly involved in the preparation of this report, has a financial interest in the securities of the subject company. Neither LSC nor any of its affiliates beneficially own 1% or more of any class of common equity securities of the subject company.

LSC is a member of FINRA and SIPC. Information has been obtained from sources believed to be reliable but LSC or its affiliates (LifeSci Advisors, LLC) do not warrant its completeness or accuracy except with respect to any disclosures relative to LSC and/or its affiliates and the analyst's involvement with the company that is the subject of the research. Any pricing is as of the close of market for the securities discussed, unless otherwise stated. Opinions and estimates constitute LSC's judgment as of the date of this report and are subject to change without notice. Past performance is not indicative of future results. This material is not intended as an offer or solicitation for the purchase or sale of any financial instrument. The opinions and recommendations herein do not take into account individual client circumstances, objectives, or needs and are not intended as recommendations of particular securities, companies, financial instruments or strategies to particular clients. The recipient of this report must make his/her/its own independent decisions regarding any securities or financial instruments mentioned herein. Periodic updates may be provided on companies/industries based on company specific developments or announcements, market conditions or any other publicly available information. Additional information is available upon request.