Setting "Cyts" on Complementary NK Cells with All-Share CytoSen Acquisition

17 April 2019

Key Takeaway

Kiadis is acquiring privately held CytoSen in a small but intriguing deal. This brings a complementary cell-based technology platform and Phase II ready product that theoretically could be combined with Kiadis' ATIR101 for half-matched stem cell transplants (haplo-ID HSCT) to improve outcomes. A Phase II study with lead product CSTF002-NK in haplo-ID HSCT is planned to start in 2020E. Separately, ATIR101 remains on track for EU approval by YE19E.

CytoSen brings NK cell technology to complement Kiadis' T-cells

CytoSen's technology platform is based around natural killer cells (NK cells) a type of lymphocyte (white blood cell) that is part of the innate immune system. NK cells can potentially play a role in lowering the risk of relapse in the first few months after a haematopoietic stem cell transplant (HSCT) as they are the first white blood cells to reconstitute, in addition to preventing infections and improving mortality. Given innate NK and adaptive T-cells form the basis of the immune system, synergistic therapeutic approaches could improve patient outcomes. Hence, the combination with T-cell based ATIR101, which aims to minimise the life threatening risk of graft versus host disease (GvHD) in half-matched haploidentical (haplo-ID) transplants, presents an intriguing cell therapy combination, assuming tolerability is manageable. Data will be needed to confirm this hypothesis.

Lead product CSTF002-NK has completed a 25 patient academic study in haplo-ID HSCT, with an 8% relapse rate and 66% progression-free survival (PFS), not dissimilar to the 9% relapse rate reported with ATIR101 in Phase II trials. A Phase II study in haplo-ID HSCT AML patients is due to start 2020E.

All-share deal with small initial c.€19m upfront and future success based milestones

Kiadis will issue 1.94m (7.4%) shares to CytoSen holders, worth c.€19.4m/$22m based on the prior day close. Up to 5.82m additional Kiadis shares could be issued to CytoSen shareholders on achieving six specific clinical and regulatory milestones, with the final milestone on FDA approval of a CytoSen product. Kiadis gains $6m of cash, a small boost to the €49m cash at 31 Mar '19. Cell therapy pioneer Dr Carl June will join Kiadis' scientific advisory board.

ATIR101 CHMP responses to be submitted by end May; launch on track for 2H19E

Kiadis has outlined that it expects to respond to the EMA's October information request by the end of May, as part of the ongoing European marketing authorisation application (MAA) for ATIR101. Recall the EMA requested further information from Kiadis related to the original responses to the "Day 180 List of Outstanding Issues". We understand the information is mainly focused on additional analysis of existing data, without the need for new clinical data. Assuming this restarts the typical 210 day review clock, we could therefore receive an initial CHMP opinion potentially in June or July. This would still allow for formal EMA approval 3Q19E and launch by YE19E, in-line with our current forecasts.

We note that timing for interim data from the ongoing Phase III HATCY trial in the US is now more conservatively 2021E (was 2H20E). Our forecasts continue to assume that the trial runs to full completion before US filing.

FLASH NOTE	
RATING	BUY
TICKER	KDS NA
PRICE	€9.98^
PRICE TARGET (PT)	€23.00
MARKET CAP	€242.5M / $274.0M

^Prior trading day's closing price unless otherwise noted.

Philippa Gardner, Eng.D. *
Equity Analyst
+44 (0) 20 7029 8675
pgardner@jefferies.com

Peter Welford, CFA *
Equity Analyst
+44 (0) 20 7029 8668
pwelford@jefferies.com

Lucy Codrington *
Equity Analyst
+44 (0) 20 7029 8570
lcodrington@jefferies.com

Colin White, PhD *
Equity Associate
+44 (0) 20 7029 8538
cwhite3@jefferies.com

Company Description

Kiadis

Kiadis develops innovative cell therapies for safer and more effective bone marrow transplants. Its Allodepleted T-cell ImmunotheRapeutics (ATIR) are based on the Theralux platform. Lead programme ATIR101 is filed in Europe for haploidentical haematopoietic stem cell transplants (HSCT) in patients with blood cancers. Kiadis is based in The Netherlands and listed on the Euronext Amsterdam in July 2015.

Company Valuation/Risks

Kiadis

Our Price Target is based on a sum-of-the-parts valuation comprising probability-adjusted NPVs for ATIR in the US and EU, together with Net Cash, less potential dilution to ensure sufficient funds until YE2020E. Risks include: (1) clinical or regulatory setbacks; (2) commercial execution risks; and (3) securing adequate funds to maximise value.

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(Article 3(1)e and Article 7 of MAR)

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Distribution of Ratings						
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