FLASH NOTE

Company Update

Netherlands | Healthcare | Biotechnology

12 October 2018

Jefferies

Kiadis (KDS NA)

ATIR101 CHMP Decision Shifts to 1H19E but European 2H19E Launch Unaffected

BUY

Bloomberg NXT AM: KDS NA
Price target €25.00
Price €13.06^

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

EQUITY RESEARCH EUROPE

Key Takeaway

The EU regulator has requested further information to review the ATIR101 filing, delaying the upcoming CHMP opinion on conditional approval into 1H19E. Whilst this may disappoint, we highlight: (1) no new clinical data have been requested, which is reassuring; and (2) initial EU launch remains on-track for 2H19E, in-line with our current forecasts. Given reiterated timelines, there is no impact or fundamental change to our Buy thesis or €25 Price Target.

CHMP opinion shifts to 1H19E: The European EMA regulator has requested further information from Kiadis regarding the marketing authorisation application (MAA) for ATIR101. Recall in August Kiadis submitted responses to the "Day 180 List of Outstanding Issues". We understand the latest information request relates to aspects of these Day 180 questions, with additional analysis of existing data required. Importantly, no new clinical data have been requested. Given the nature of the request, we believe Kiadis should be able to provide responses in a few months, which should allow for a CHMP opinion during 1H19E, including time for the EMA to review the file.

EU launch remains on track for 2H19E: Despite the delay to the CHMP opinion, Kiadis is still targeting a 2H19E initial EU launch, in-line with our current forecasts. The launch timing has not been impacted as this had conservatively allowed more than adequate time to ramp-up manufacturing and for market access discussions. These remain ongoing, running in parallel with the regulatory review.

US trial recruitment ramping-up; interim data still 2H20E: The ongoing Phase III HATCY trial continues to progress, with 22 patients enrolled, an encouraging increase from the 16 patients enrolled at end-August. The interim analysis is still anticipated 2H20E. Our forecasts conservatively assume that the trial runs to full completion before US filing, with initial US launch from 2H22E and meaningful sales from 2023E. If the interim is positive, we estimate launch and sales could come around one year sooner.

ATIR addresses an unmet need: Haematopoietic stem cell transplants (HSCT) can offer a cure for some serious disorders but it can be challenging to find matched donors, whereas haploidentical are widely available. Current protocols mitigate the life-threatening risk of graft versus host disease (GvHD), but typically also subdue graft versus leukaemia (GvL) antitumour and anti-infective benefits. ATIR aims to minimize GvHD while retaining the benefits, lowering the risk of relapse and complications. Phase II confirmed this potential, comparing very favourably for GvHD and relapse risks relative to literature reports for current standard-of-care PTCy, in our view.

ATIR could boost HSCT: We forecast "half-matched" haplo-ID HSCT to more than double by 2026E, driven by protocols such as PTCy and potentially ATIR, for which we expect launch from 2H19E EU and 2022E US. Assuming 20% peak ATIR penetration with €150k/ $250k average Revenue/patient we derive $230m/$250m EU/US peak sales for c.€19/€7 per share NPV at 80%/50% probability. "Best" case we believe ATIR peak sales could near-$2bn.

Adequate funds to launch ATIR in Europe: Funds of c.€42m cash at end June, together with the €20m debt facility, should be sufficient to fund burn into 2020E, excluding any possible out-licensing deals or other income. Importantly this should be beyond the EU approval and launch, and could potentially also be sufficient to reach the Phase III HATCY interim analysis 2H20E depending on the event rate and speed of patient enrolment. However, incremental funds may be necessary for S&M and submitting the US filing if the interim is positive, or completing the Phase III, in our view.

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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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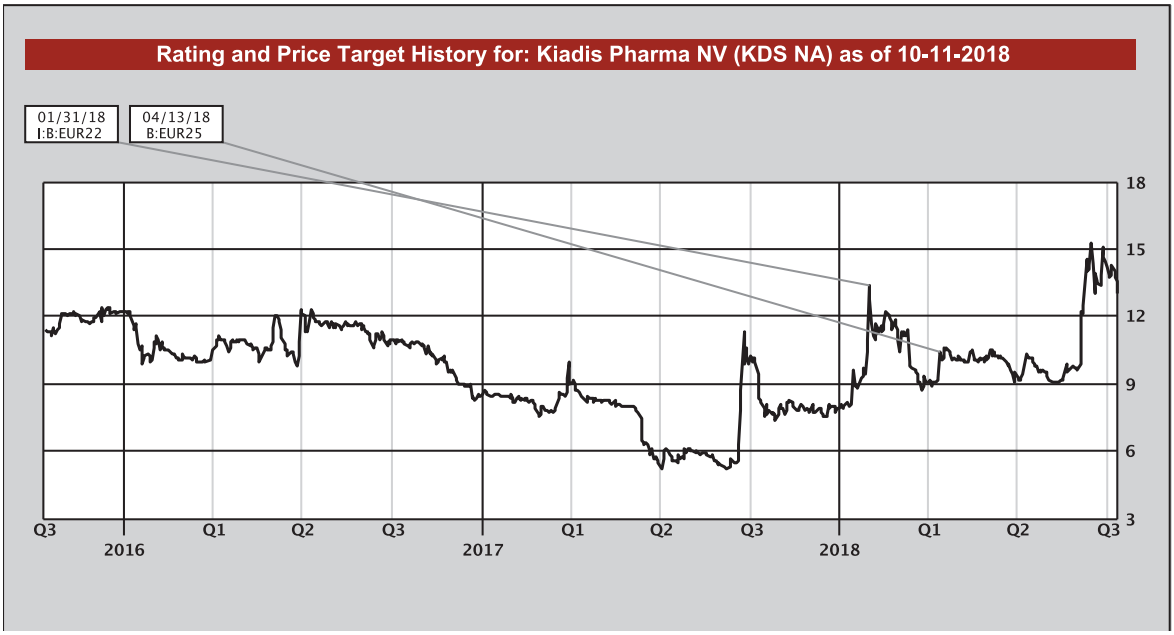
Other Companies Mentioned in This Report

- Kiadis Pharma NV (KDS NA: €13.06, BUY)



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