FLASH NOTE

Company Update

Netherlands | Healthcare | Biotechnology

31 August 2018

Jefferies

Kiadis (KDS NA)

1H Confirms EU Timelines but US Prolonged on Enlarged Phase III

BUY

Bloomberg NXT AM: KDS NA
Price target €25.00
Price €9.68^

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

EQUITY RESEARCH EUROPE

Key Takeaway

The ATIR EU CHMP opinion remains on track for 4Q18E, the key upcoming catalyst. Timelines for the ATIR Phase III trial have been prolonged, with the trial enlarged and the interim analysis set to be after 2/3 events, with readout expected 2H20E from previous 1H19E, impacting US launch timelines. Recruitment is on track, with 14 sites of the planned 50 now open and 16 patients enrolled. 1H spend is in-line with higher interest expense driving a wider net loss.

ATIR EU timelines on track: The main near-term catalyst is the EU CHMP opinion which importantly, remains on track for 4Q18E for conditional approval 1Q19E. Kiadis submitted responses to the Day 180 questions in August which could allow for CHMP review at an upcoming meeting in the next few months.

ATIR Phase III trial enlarged prolonging US timelines: The Phase III trial is progressing as expected, with 14 of the 50 planned sites now open and 16 patients enrolled. To de-risk the Phase III outcome, Kiadis has opted to enlarge the Phase III trial to now include 250 patients, an increase from the original 195 patients. The interim analysis is also now set to occur after two-thirds rather than at half the events. The interim read-out is therefore now anticipated 2H20E from our previous 1H19E expectations. If the interim is positive, which is possible based on the increased size and number of events, then US launch will potentially only be a few months behind our current forecast, which assumes launch in 2022E. However, if the trial needs to continue to full completion, then this could potentially delay US launch beyond 2023E.

Funded beyond key catalysts: Kiadis reported €41.7m cash at end June, which together with the recently secured €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 rate 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.

1H operating spend in-line: 1H financials are not material, with R&D and G&A in-line, but higher interest income to service debt drives a wider net loss.

- R&D €7.7m vs. JEFe €7.6m
- G&A €3.4m vs. JEFe €3.4m
- Net Loss €14.1m vs JEFe €11.8m

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.

Nearing green light for ATIR to boost HSCT: We forecast 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 $245m/$235m EU/US peak sales for c.€18/€9 per share NPV at 80%/50% probability. "Best" case we believe ATIR peak sales could near-$2bn.

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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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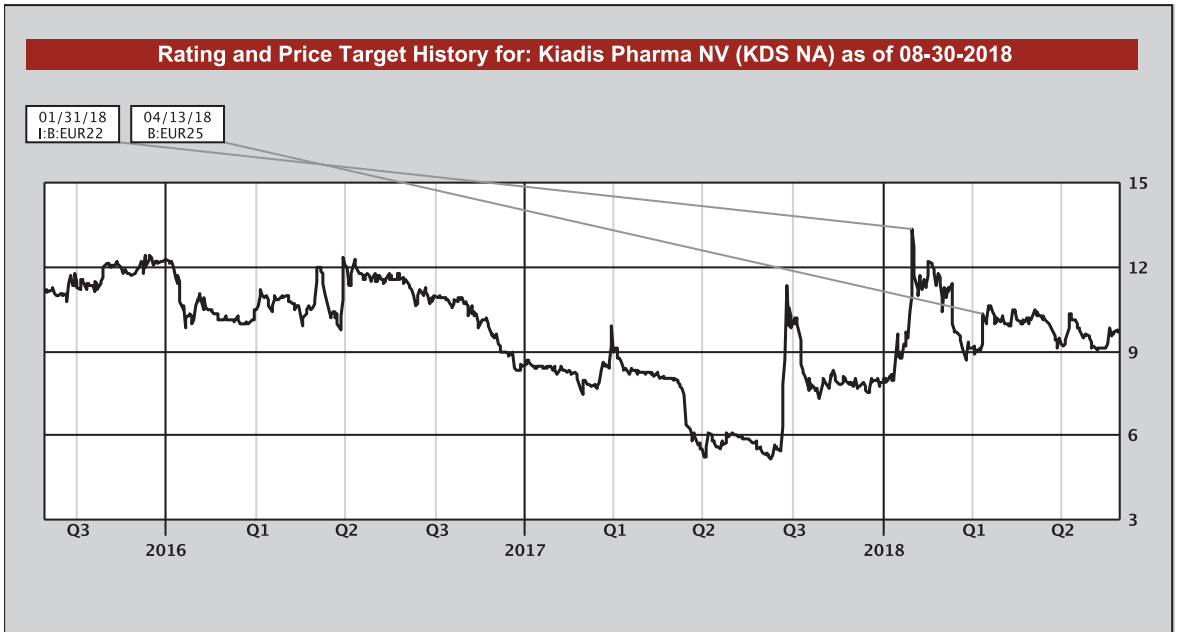

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