# ATIR101 on track for YE19 launch with timely EMA response submission

23 May 2019

## Key Takeaway

**Kiadis has submitted responses to the European regulator's second set of outstanding issues. Whilst expected, the timing is nevertheless welcome as it should allow for ATIR101 review as an add-on to "half-matched" haplo-ID bone marrow transplants for an initial CHMP opinion by mid-19E, likely ahead of the CHMP summer break in August. A positive opinion by mid-19E would allow for formal approval and initial ATIR101 launch by YE19E, in-line with our expectations.**

### ATIR101 response submission should allow for CHMP opinion by mid-19E

With responses now submitted to the second set of "Day 180 List of Outstanding Issues" as part of the ongoing European marketing authorisation application (MAA) for ATIR101, Kiadis remains on-track for initial launch by YE19E. Assuming the submission restarts the typical 210 day review clock, an initial CHMP opinion could come around mid-19E. The next CHMP meeting is scheduled 24-27 June, although we believe an opinion is more likely at the 22-25 July meeting, ahead of the typical break in August. Following the CHMP opinion, a formal EMA decision usually takes 67 days.

### European launch remains on track with initial patients treated by YE19E

Our ATIR101 launch forecasts assume that only a few patients receive commercial ATIR101 treatment by YE19. We expect fairly moderate sales in initial launch years given eligible patients are more likely to be included in the ongoing Phase III trial, which includes key European centres, in addition to the time taken to secure broad pricing and reimbursement across the major EU markets. We, therefore, do not expect a full commercial roll-out until the last patient has been recruited in the Phase III trial, expected during 2021E.

### Phase III trial ongoing towards US approval with interim data 2021E

The international Phase III HATCY trial is ongoing, with an interim analysis anticipated 2021E. Kiadis has announced plans to collaborate with Be The Match BioTherapies to facilitate cell therapy delivery and processing as part of the clinical trial.

### 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.

### ATIR101 could boost HSCT

We forecast half-matched haplo-ID HSCT to more than double by 2026E, driven by protocols such as PTCy and potentially ATIR101, for which we expect launch from 2H19E EU and 2023E US. Assuming 20% peak ATIR101 penetration with €150k/ $250k average Revenue/patient we derive $220m/$240m EU/US peak sales for c.

| FLASH NOTE | |
|---|---|
| RATING | BUY |
| TICKER | KDS NA |
| PRICE | €9.07^ |
| PRICE TARGET (PT) | €16.00 |
| MARKET CAP | €220.4M / $246.4M |

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

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€14/€6 per share NPV at 80%/50% probability. Best case we believe ATIR101 peak sales could near-$2bn.

## 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 ATIR101 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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|---|---|
| Recommendation Published | May 23, 2019 , 02:24 ET. |
| Recommendation Distributed | May 23, 2019 , 02:24 ET. |

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| Distribution of Ratings | | | | | | |
|---|---|---|---|---|---|---|
| | | | IB Serv./Past12 Mos. | | JIL Mkt Serv./Past12 Mos. | |
| | Count | Percent | Count | Percent | Count | Percent |
| BUY | 1146 | 54.18% | 89 | 7.77% | 15 | 1.31% |
| HOLD | 822 | 38.87% | 11 | 1.34% | 1 | 0.12% |
| UNDERPERFORM | 147 | 6.95% | 1 | 0.68% | 0 | 0.00% |

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