EDISON

Kiadis Pharma

Clinical data update

One-year follow-up data presented at ASH

Pharma & biotech

Kiadis Pharma has presented one-year follow-up data from a Phase II study in leukaemia patients (n=23) at the 58th meeting of the American Society of Hematology (ASH) in San Diego, US. Patients were administered ATIR101 after a haematopoietic stem cell transplant (HSCT) from a partially matching donor. The primary endpoint of transplant-related mortality (TRM) and secondary endpoint overall survival (OS) for patients receiving HSCT+ATIR101 were significantly higher than patients receiving HSCT alone from an observational control group. We are encouraged to see the low incidence of relapse in the ATIR101 arm in this high-risk patient population. Our valuation is €383.2m or €27.4 per share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14	0.00	(7.21)	(0.07)	0.0	N/A	N/A
12/15	0.00	(17.35)	(0.14)	0.0	N/A	N/A
12/16e	0.00	(9.99)	(0.07)	0.0	N/A	N/A
12/17e	0.00	(13.48)	(0.10)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

ATIR101: Increasingly positive data at one year

In this open-label single dose Phase II study, ATIR101 administered after HSCT showed a significant reduction in the primary endpoint of TRM at 32% vs 70% for HSCT only (p=0.007) of a historical comparator group. Overall survival was 61% for HSCT+ATIR101 vs 20% for HSCT only (p=0.0023). There were no cases of grade III-IV acute Graft vs Host Disease (GVHD), only three cases of grade II acute GVHD, and one chronic GVHD. Thus, event-free survival rate (GRFS) was 57% after one year, which is higher than 20% for the historic group, even for matching unrelated donors (41%) and post-transplant cyclophosphamide (PTCy) of 33% as reported by Solh et al. (2016).

Up next: Start Phase III trial and EU filing

Kiadis plans to initiate a Phase III trial in patients with acute leukaemia soon after regulatory approval of the protocol (we assume Q117). Patients will be randomised to receive a single dose of ATIR101 or PTCy after haploidentical HSCT. Furthermore, on the back of the Phase II data, the company plans to submit a Marketing Authorization Application for conditional approval to the European Medicines Agency (EMA) in Q117. ATIR201 will start clinical testing in thalassemia in H216.

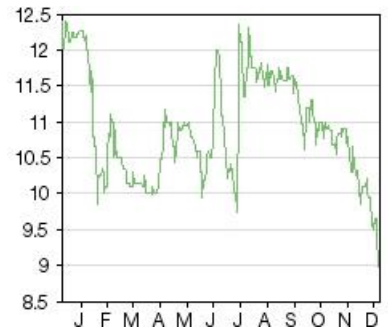
Valuation: Upgraded to €383.2m from €327.3m

We are slightly increasing the probability of success for ATIR101 in the EU from 70% to 75% to reflect our positive stance on Kiadis receiving EMA approval based on positive Phase II data and the precedent of MolMed, which received conditional approval on lower one-year survival data of 49%. We are also rolling the valuation forward in time. This results in an increased rNPV valuation of €383.2m vs previous €327.3m.

8 December 2016

Price	**€8.98**
Market cap	**€125m**
	US$1.11/€
Net cash (€m) at June 2016 (excludes Hospira debt)	16.2
Shares outstanding	13.97m
Free float	31.1%
Code	KDS
Primary exchange	Euronext Amsterdam
Secondary exchange	Euronext Brussels

Share price performance



%	1m	3m	12m
Abs	(15.7)	(19.9)	(26.3)
Rel (local)	(18.3)	(19.7)	(28.5)
52-week high/low		€12.4	€9.0

Business description

Kiadis Pharma is a Dutch biotech company focused on cell-based immunotherapies to overcome complications associated with stem cell transplants in blood diseases. Lead product ATIR101 for leukaemia is undergoing a Phase II trial and will file for EU approval in Q117. ATIR201 is in preclinical stage and has potential for thalassemia. A Phase I/II study will start in H216.

Next events

ATIR101 Phase III start	H216
ATIR201 Phase I/II start	H216
ATIR101 EU filing	Q117
ATIR101 two-year data	H217

Analysts

Juan Pedro Serrate +44 (0)20 3681 2534

Lala Gregorek +44 (0)20 3681 2527

healthcare@edisongroup.com

Edison profile page

One-year Phase II data confirms efficacy of ATIR101

Kiadis Pharma has presented one-year data of its ongoing Phase II trial in patients with acute leukaemia subject to HSCT at the 58th meeting of the ASH. This is a multicentre, open-label Phase II trial (NCT01794299, CR-AIR-007) evaluating the safety and efficacy of a T-cell depleted haploidentical transplant followed by ATIR101 infusion at a median of 28 days post-transplant. The primary endpoint is TRM; relevant secondary endpoints are OS and progression-free survival. The trial included 23 patients (16 with acute myeloid leukaemia and seven with acute lymphoblastic leukaemia) who were in first or second remission. Most patients (57%) had a high or very high risk of leukaemia; the rest had an intermediate risk. Patients did not receive post-transplant GVHD prophylaxis.

There was no TRM after 100 days of treatment. There were seven deaths in the ATIR101 arm as a result of TRM at one year post-HSCT, resulting in a TRM rate of 32%. All seven patients died from infection. In addition, two patients died from disease relapse, resulting in an overall survival of 61%. There were no cases of grade III-IV acute GVHD and only three of grade II acute GVHD. One patient had chronic GVHD.

Exhibit 1: Phase II clinical data at one-year follow up

Endpoint	HSCT+ ATIR101	HSCT only
TRM	32%	70%
OS	61%	20%
GFRS	57%	20%
Grade III/IV acute GVHD	0%	N.D.
Grade II acute GVHD	13%	N.D.
Chronic GVHD	4.3%	N.D.

Source: Edison Investment Research, Kiadis Pharma. Note: N.D. = not disclosed.

These data compare favourably with a historic control group obtained from the same centres and with the same inclusion/exclusion criteria that had undergone a transplant from haploidentical family members (NCT02188290/CR-AIR-006). When compared to the control group (n=35), TRM was significantly lower in patients given ATIR101 after a T-cell depleted haplo HSCT with a one-year TRM of 32% versus 70% for HSCT only (p=0.007). Overall survival was significantly higher in the HSCT+ATIR101 group (61%), compared to HSCT alone (p=0.0023).

Event-free survival, defined as GVHD-free, relapse-free survival (GRFS[1]), was 57% after one year in the HSCT+ATIR101 group, which is higher than 20% for the HSCT-only group. Interestingly, this result is also higher than matching unrelated donors (41%) in the same group. According to Sol(h et al. (2016), patients receiving cyclophosphamide after haploidentical HSCT had a GFRS of 33%.

EU registration and Phase III plans on track

We expect the full Phase III trial to start in Q117. The protocol has been submitted to regulatory authorities in the EU and US and is currently under review for approval. Patients will receive either ATIR101 or the Baltimore approach (PTCy) after haploidentical HSCT. The primary endpoint of the Phase III trial will be GFRS. Moreover, Kiadis anticipates an EU regulatory filing in Q117 on the back of the Phase II results. Additionally, ATIR101 is undergoing a Phase II study in which a second dose of the product is administered to patients before the 100-day period post-transplantation to support faster immune-reconstitution. The full enrolment and safety readout will be completed in H217.

[1] It is a composite endpoint that measures survival free of morbidity defined as grade III-IV aGVHD, cGVHD requiring systemic treatment, cancer relapse, or death.

The second product, ATIR201 for thalassemia, is currently in a preclinical stage. A Phase I/II programme is slated to start H217. The development pipeline is summarised in Exhibit 2.

Exhibit 2: Kiadis Pharma product portfolio

Product	Indication	Status	Potential launch	Comments
ATIR101	Leukaemia	Phase II	2018	Presented positive data at six months and one year. Regulatory filing in EU in Q117. Phase III start in Q117.
ATIR201	Thalassemia	Preclinical	2022	Preclinical stage. Start Phase I/II trial in H216.

Source: Edison Investment Research, Kiadis Pharma

Valuation: Increasing to €383.2m or €27.4/share

We are upgrading our rNPV valuation to €383.2m or €27.4 per share vs our previous €327.3m. We are slightly increasing the probability of receiving EMA approval for ATIR101 from 70% to 75% based on positive Phase II data and following the precedent of MolMed, which received conditional approval on lower one-year survival data of 49%. We are also rolling the valuation forward by half a year. Our underlying financial forecasts remain unchanged.

We are not including ATIR201 in the valuation as it is in the preclinical stage. We will revisit our rNPV model once clinical data are released.

Exhibit 3: Kiadis Pharma rNPV valuation

Product	Indication	Launch	Peak sales (US$m)	Probability	rNPV (€m)	rNPV/share (€)
ATIR101 EU	Leukaemia	2018	227.8	75%	351.9	25.2
ATIR101 US	Leukaemia	2020	273.3	50%	237.9	17.0
Expenses					214.4	15.4
Net cash June 2016*					7.7	0.6
Number of shares						**13.97m**
Valuation					**383.2**	**27.4**

Source: Edison Investment Research. Note: *Includes Hospira debt.

Exhibit 4: Financial summary

€'000s	2013	2014	2015	2016e	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	0	0	0	0	0	3,906
Cost of Sales	0	0	0	0	0	(1,953)
Gross Profit	0	0	0	0	0	1,953
R&D expenses	(3,548)	(4,692)	(7,715)	(7,230)	(10,000)	(10,000)
SG&A expenses	(1,444)	(1,476)	(8,292)	(1,476)	(2,000)	(4,000)
EBITDA	(4,890)	(6,042)	(15,867)	(8,606)	(11,900)	(12,142)
Operating Profit (before GW and except.)	(4,992)	(6,168)	(16,007)	(8,706)	(12,000)	(12,242)
Intangible Amortisation	0	0	0	0	0	0
Exceptionals/Other	0	0	0	0	0	0
Operating Profit	(4,992)	(6,168)	(16,007)	(8,706)	(12,000)	(12,242)
Net Interest	(831)	(1,045)	(1,344)	(1,284)	(1,476)	(1,473)
Exceptionals	0	0	0	0	0	0
Other	(1,062)	(598)	894	0	0	0
Profit Before Tax (norm)	(5,823)	(7,213)	(17,351)	(9,990)	(13,476)	(13,715)
Profit Before Tax (IFRS)	(6,885)	(7,811)	(16,457)	(9,990)	(13,476)	(13,715)
Tax	0	(2)	(1)	0	0	0
Discontinued operations	0	0	0	0	0	0
Profit After Tax (norm)	(6,885)	(7,813)	(16,458)	(9,990)	(13,476)	(13,715)
Profit After Tax (IFRS)	(6,885)	(7,813)	(16,458)	(9,990)	(13,476)	(13,715)
Average Number of Shares Outstanding (m)	10.90	10.47	12.06	13.97	13.97	13.97
EPS - normalised (€)	(0.06)	(0.07)	(0.14)	(0.07)	(0.10)	(0.10)
EPS - IFRS (€)	(0.06)	(0.07)	(0.14)	(0.07)	(0.10)	(0.10)
Dividend per share (€)	0.00	0.00	0.00	0.00	0.00	0.00
Gross Margin (%)	N/A	N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets	13,428	14,100	13,047	13,047	13,047	13,047
Intangible Assets	13,148	13,687	12,714	12,614	12,514	12,414
Tangible Assets	280	413	333	433	533	633
Other	0	0	0	0	0	0
Current Assets	6,760	6,112	29,229	19,239	17,763	3,852
Stocks	0	0	0	0	0	98
Debtors	51	196	145	145	145	391
Cash	6,482	5,674	28,666	18,676	17,200	2,946
Other	227	242	418	418	418	418
Current Liabilities	(1,619)	(8,727)	(2,913)	(1,747)	(1,746)	(1,745)
Creditors	(1,235)	(1,598)	(1,747)	(1,747)	(1,747)	(1,747)
Short term borrowings	(384)	(7,129)	(1,166)	0	0	0
Deferred revenues	0	0	0	0	0	0
Other short term liabilities	0	0	0	0	1	2
Long Term Liabilities	(13,210)	(8,820)	(13,713)	(14,879)	(26,879)	(26,684)
Long term borrowings	(10,021)	(5,090)	(13,713)	(14,879)	(26,879)	(26,684)
Deferred revenues	0	0	0	0	0	0
Other long term liabilities	(3,189)	(3,730)	0	0	0	0
Net Assets	5,359	2,665	25,650	15,660	2,185	(11,529)
CASH FLOW						
Operating Cash Flow	(4,369)	(6,062)	(7,955)	(8,606)	(11,900)	(12,485)
Net Interest	(28)	(13)	(141)	(1,284)	(1,476)	(1,473)
Tax	0	0	0	0	0	0
Capex	(102)	(259)	(59)	(100)	(100)	(100)
Acquisitions/disposals	0	0	1	2	3	4
Financing	0	5,051	31,229	0	0	0
Dividends	0	0	0	0	0	0
Other	89	28	4	0	0	0
Net Cash Flow	(4,410)	(1,255)	23,079	(9,988)	(13,473)	(14,055)
Opening net debt/(cash)	(505)	3,923	6,545	(13,787)	(3,797)	9,679
HP finance leases initiated	0	0	0	0	0	1
Exchange rate movements	25	(8)	22	0	0	0
Other	(43)	(1,359)	(2,769)	(2)	(3)	(5)
Closing net debt/(cash)	3,923	6,545	(13,787)	(3,797)	9,679	23,738

Source: Edison Investment Research, Kiadis Pharma accounts

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 9258 1161
Level 25, Aurora Place
88 Phillip St, Sydney
NSW 2000, Australia

Wellington +64 (0)48 948 555
Level 15, 171 Featherston St
Wellington 6011
New Zealand