

Celyad ASH update

Blasts get blasted but dose needs definition

Data at ASH on 3 December confirmed that CYAD-01 T-cells can destroy acute myeloid leukaemia (AML) blast (cancer) cells. In eight reported AML patients, there was a 62% (5/8) response rate across three dose levels. As preconditioning was not used, this rate is impressive. Safety was excellent with only one dose-limiting toxicity event at a high dose. The good safety profile should now enable faster progress to determine the optimal dose schedule. Further data are promised in H119, probably mid-year. A study combining CYAD-01 with preconditioning is underway and may be crucial. The indicative value is still €1,090m (€89 per share) pending further data.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	8.52	(20.00)	(2.09)	0.0	N/A	N/A
12/17	3.54	(26.80)	(2.79)	0.0	N/A	N/A
12/18e	0.00	(27.25)	(2.43)	0.0	N/A	N/A
12/19e	0.00	(28.50)	(2.38)	0.0	N/A	N/A

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

Lots of detail but no clear dose response in AML

In the reported open-label THINK study to date, 14 patients were dosed of whom eight were relapsed or refractory (r/r) cases, so small numbers to date. AML is a very aggressive and mutationally varied cancer affecting individuals usually from their late 60s. Three r/r AML patients showed complete remission (38%), but due to prior chemotherapies, none had a full haematological recovery. One, treated at the low dose (3x10⁸) in November 2017, proceeded to a stem cell transplant; the best outcome to date. Long-term persistence of CYAD-01 cells is needed for disease control, but one course (three infusions) at a low dose is insufficient to control blasts for more than a few months at best. Multiple CYAD-01 courses are needed. Crucially, the NKG2D receptor used in CYAD-01 is not immunogenic so CYAD-01 can be repeatedly dosed. All patients showed high levels of the NKG2D ligands targeted by CYAD-01, especially the heterogeneous MICA and MICB ligands.

Next AML data by mid-2019

The THINK study will recruit a further cohort to test multiple dosing: six injections over two months; data are promised in H119 (probably mid-year). A further 21-patient study now running is DEPLETHINK; initial data due in H119. This uses preconditioning (Cy-Flu lymphodepletion) to drive *in vivo* CYAD-01 expansion. Early solid cancer data from SITC (Nov 2018) indicates CYAD-01 can expand further after preconditioning. In our view, CYAD-01 still needs higher, consistent CR rates and survival data to progress into further pivotal studies. This probably just needs more patients to be studied at high doses. CYAD-01 safety now seems established.

Valuation: Unchanged at €1,090m pending more data

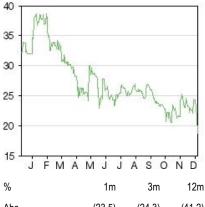
The overall indicative value remains €1,090m, €89 per share based on a 25% probability of success in AML. The timing, design and costs of pivotal studies are still not determined, and this will affect future value estimates. A multiple dose therapy will be expensive and will need reliable outcomes for strong sales.

Pharma & biotech

7 December 2018

Price	€18.66
Market cap	€223m
	\$1.18/€
Cash (€m) at 30 September 201	8 55.9
Shares in issue	11.94m
Free float (Edison estimate)	67%
Code	CYAD
Primary exchange	Euronext Brussels
Secondary exchange	NASDAO

Share price performance



%	1m	3m	12m
Abs	(23.5)	(24.3)	(41.2)
Rel (local)	(19.5)	(16.8)	(29.6)
52-week high/low		€38.7	€18.7

Business description

Celyad is developing an innovative natural killer receptor (NKR) CAR T-cell immune-oncology platform. Celyad has a leading position in CAR for AML and solid tumours and is exploring the use of NKR CAR with chemotherapy. It holds a key granted patent in allogeneic CAR technology.

Next events

Further data	H1 (mid) 2019
FY18 results	Q119

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Edison profile page

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	€000s	2016	2017	2018e	2019
Year end 31 December	· · · · · · · · · · · · · · · · · · ·	IFRS	IFRS	IFRS	IFR
PROFIT & LOSS					
Revenue		8,523	3,540	0	
Cost of Sales		(53)	(515)	(500)	(500
Gross Profit		8,470	3,025	(500)	(500
EBITDA	(21,246)	(22,317)	(26,500)	(27,750
Operating Profit (before amort. and except).		22,006)	(23,283)	(27,500)	(28,750
Intangible Amortisation		(756)	(748)	(750)	(750
Other income and charges		0	(26,273)	0	,
Share-based payments		(2,847)	(2,569)	(2,600)	(2,600
Operating Profit	(25,609)	(52,873)	(30,850)	(32,100
Net Interest	,	1,997	(3,521)	250	250
Profit Before Tax (norm)	(20,009)	(26,804)	(27,250)	(28,500
Profit Before Tax (FRS 3)		23,612)	(56,394)	(30,600)	(31,850
Tax		6	(30,334)	(50,000)	(31,030
Profit After Tax (norm)		20,003)	(26,803)	(27,250)	(28,500
Profit After Tax (FRS 3)		23,606)		(30,600)	
, ,		,	(56,393)	,	(31,850
Average Number of Shares Outstanding (m)		9.3	9.6	11.2	12.
EPS - normalised (c)		(209)	(279)	(243)	(238
EPS - (IFRS) (c)		(253)	(586)	(273)	(267
Dividend per share (c)		0.0	0.0	0.0	0.0
Gross Margin (%)		N/A	N/A	N/A	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N//
Operating Margin (before GW and except) (%)		N/A	N/A	N/A	N/A
		IN/A	111/7	IN/A	IN//
BALANCE SHEET					
Fixed Assets		53,440	41,232	40,492	39,752
ntangible Assets		49,566	36,508	35,768	35,028
Tangible Assets		3,563	3,290	3,290	3,290
nvestments		311	1,434	1,434	1,434
Current Assets		85,366	36,393	50,659	22,149
Stocks		0	0	0	(
Debtors		1,359	233	233	233
Cash (cash plus deposits)		82,587	33,905	48,171	19,66
Other		1,420	2,255	2,255	2,25
Current Liabilities		(11,275)	(7,944)	(7,944)	(7,944
Creditors	·	(9,960)	(7,509)	(7,509)	(7,509
Deferred revenue		0	0	0	(1,000
Walloon loans and bank loan		(1,315)	(435)	(435)	(435
Long Term Liabilities	-	(1,515)	(22,146)	(22,146)	(22,146
Loans (non-current) Bank and Walloon		(7,866)	(1,870)	(1,870)	(1,870
		28,780)			
Other long term liabilities		, ,	(20,276)	(20,276)	(20,276
Net Assets		90,885	47,535	61,061	31,81
CASH FLOW					
Operating Cash Flow	(26,695)	(46,027)	(26,514)	(27,471
Net Interest		1,997	(3,521)	264	(29
Гах		0	0	0	. (
Capex		(1,782)	(858)	(1,010)	(1,010
Acquisitions/disposals		(1,561)	Ó	Ó	, ,
Financing		0	625	46,140	
Dividends		0	0	0	
Other		3,109	1,099	(4,614)	
Net Cash Flow		24,932)	(48,682)	14,266	(28,510
Opening net debt/(cash)					(45,866
1 0 1		96,131)	(73,406)	(31,600)	• •
HP finance leases initiated		2 207	0	0	(
Loan and finance movements		2,207	6,876	(0)	(47.050
Closing net debt/(cash)		73,406)	(31,600)	(45,866)	(17,356



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