

Celyad

Allogeneic trial approved in colorectal cancer

Allo IND approval

Pharma & biotech

The FDA's sign off on Celyad's first clinical trial design for its allogeneic NRK CAR T-cell therapy (CYAD-101) is an important milestone. The study, possibly starting in Q4 2018, mirrors the current colorectal SHRINK trial a combination of autologous CYAD-01 therapy with FOLFOX chemotherapy. This gives Celyad the lead in a mass-market solid cancer where allogeneic therapy is likely to be essential. The indicative value has been increased to €1,090m (€89 per share) from €1,040m (€84 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.

Leading position in solid cancers and allogeneic cells

NKR CAR T-cell therapy is a generalised approach targeting "stressed" cancer cells, for example, after chemotherapy like FOLFOX. Combined with an allogeneic approach, this offers a more affordable, rapid -response potential therapy for many thousands of patients. This gives Celyad the dominant position in solid cancers, an area other CAR therapies find hard to access ([see report](#)). Celyad is already evaluating autologous (customised) CYAD-01 with FOLFOX in the [SHRINK](#) trial and the approved IND mirrors that trial design. SHRINK seeks to optimise the safe CYAD-01 dose and dose schedule. We are not aware of any other allogeneic CAR T-cell therapy in solid cancers and only three in haematological cancers.

Technical details – TIM to stop GvHD

A key issue for any allogeneic therapy is the potential to trigger Graft vs Host Disease (GvHD) as the CAR T-cells could, in theory, attack normal patient tissues, skin, liver and the GI tract, if they have functional T-Cell receptors. GvHD is hard to manage and can become chronic. Celyad's technology uses T-cell receptor Inhibitory Molecules (TIM) (peptides), the genes for which are included in the viral transfection of the T-cell line ([Michaux et al 2018](#)) to make an NKR CAR. TIMs stop the production of functional TCR so, in theory, stopping any GvHD. One allogeneic cell line can be cultured to produce therapy for multiple patients so cutting costs and enabling faster treatment. A factor may be the need for multiple cell lines of differing HLA-type lines to minimise host immune destruction of the CAR T-cells. Celyad holds key patents in allogeneic therapy (licensed by Novartis).

Valuation: Nominal increase to €89 per share

The nominal allogeneic value has been increased from €50m to €100m pending further data; it may come to dominate the valuation. This increases the overall indicative value to €1,090m (formerly €1,040m), €89 per share (formerly €84). Allogeneic therapy is currently a highly-active investment area, for example, the April [deal](#) involving Pfizer and pre-clinical Allogene (US\$300m start-up funding).

2 August 2018

Price **€26.02**

Market cap **€311m**

\$1.18/€

Cash (€m) at 31 December 2017 34

Shares in issue 11.94m

Free float (Edison estimate) 67%

Code CYAD

Primary exchange Euronext Brussels

Secondary exchange NASDAQ

Share price performance



% 1m 3m 12m

Abs (0.7) (8.8) (5.9)

Rel (local) (5.7) (8.4) (4.3)

52-week high/low €54.0 €22.9

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

Q218 update Q318

THINK interim data Q418

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Exhibit 1: Financial summary

	€000s	2016	2017	2018e	2019e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		8,523	3,540	0	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	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	1	0	0
Profit After Tax (norm)		(20,003)	(26,803)	(27,250)	(28,500)
Profit After Tax (FRS 3)		(23,606)	(56,393)	(30,600)	(31,850)
Average Number of Shares Outstanding (m)		9.3	9.6	11.2	12.0
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/A
Operating Margin (before GW and except) (%)		N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets		53,440	41,232	40,492	39,752
Intangible Assets		49,566	36,508	35,768	35,028
Tangible Assets		3,563	3,290	3,290	3,290
Investments		311	1,434	1,434	1,434
Current Assets		85,366	36,393	50,659	22,149
Stocks		0	0	0	0
Debtors		1,359	233	233	233
Cash (cash plus deposits)		82,587	33,905	48,171	19,661
Other		1,420	2,255	2,255	2,255
Current Liabilities		(11,275)	(7,944)	(7,944)	(7,944)
Creditors		(9,960)	(7,509)	(7,509)	(7,509)
Deferred revenue		0	0	0	0
Walloon loans and bank loan		(1,315)	(435)	(435)	(435)
Long Term Liabilities		(36,646)	(22,146)	(22,146)	(22,146)
Loans (non-current) Bank and Walloon		(7,866)	(1,870)	(1,870)	(1,870)
Other long term liabilities		(28,780)	(20,276)	(20,276)	(20,276)
Net Assets		90,885	47,535	61,061	31,811
CASH FLOW					
Operating Cash Flow		(26,695)	(46,027)	(26,514)	(27,471)
Net Interest		1,997	(3,521)	264	(29)
Tax		0	0	0	0
Capex		(1,782)	(858)	(1,010)	(1,010)
Acquisitions/disposals		(1,561)	0	0	0
Financing		0	625	46,140	0
Dividends		0	0	0	0
Other		3,109	1,099	(4,614)	0
Net Cash Flow		(24,932)	(48,682)	14,266	(28,510)
Opening net debt/(cash)		(96,131)	(73,406)	(31,600)	(45,866)
HP finance leases initiated		0	0	0	0
Loan and finance movements		2,207	6,876	(0)	0
Closing net debt/(cash)		(73,406)	(31,600)	(45,866)	(17,356)

Source: Edison Investment Research estimates, Celyad reports and announcements

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