27th September 2016

Sector View

Biotechnology

KTE-C19 shows impressive efficacy in DLBCL

	1 M	3 M	6 M	31/12/15
Healthcare	0.0%	2.4%	5.6%	-8.3%
DJ Stoxx 600	-1.1%	5.6%	1.5%	-7.1%

*Stoxx Sector Indices

Companies covered		
CELLECTIS	**BUY**	**EUR37**
CELYAD	**NEUTRAL**	**EUR21**
INNATE PHARMA	**BUY**	**EUR18**
MORPHOSYS	**BUY**	**EUR62**
TRANSGENE		**EUR12**

ANALYSIS

- Kite Pharma yesterday announced that its Phase II evaluating KTE-C19 in patients with chemo-refractory diffuse large B cell lymphoma (DLBCL, n=51) met its primary endpoint of objective response rate or ORR (76%, including 47% of complete response).
- At first sight, this efficacy data 1/ looks superior to NVS's CTL019 in a similar setting (ORR at three months: 47%), but 2/ seems quite in line with that from JUNO's JCAR014 in aggressive NHL (ORR: 80%, CR: 50% - bearing in mind that most of these patients suffered from DLBCL). Safety-wise, note that the proportion of patients suffering from Grade ≥ 3 cytokine release syndrome (CRS) and neurological toxicity stood at 18% and 34% respectively, whereas JCAR014 showed rates more in the 10% range. In addition, two patients died from KTE-C19 related adverse events (hemophagocytic lymphohistiocytosis – a side effect associated with an over-activation of the immune system - and cardiac arrest in the setting of CRS).

	ZUMA-1 Phase 1		ZUMA-1 Phase 2					
	DLBCL (n=7)		DLBCL (n=51)		TFL/PMBCL (n=11)		Combined (n=62)	
	ORR (%)	CR (%)	ORR (%)	CR (%)	ORR (%)	CR (%)	ORR (%)	CR (%)
ORR	71	57	76	47	91	73	79	52
Month 3	43	43	39	33	64	64	44	39
Months 6 and 9	43	43			Data Pending			

VALUATION

- Overall, this data tends to confirm the efficacy and toxicity profile of anti-CD19 CAR-T candidates and could come as a relief following the negative newsflow that has affected the field in the past few months (remember the FDA clinical hold on JCAR015).
- However, fundamentally speaking, the addressable market of the current constructs (i.e. autologous ones) is likely to be limited by their toxicity profile, as well as their cumbersome manufacturing. And against this backdrop, we believe that Cellectis' first-in-class approach (allogeneic) could be a game-changing one. We hope that some preliminary data will be presented at some point in the next few months (at the ASH meeting in a best-case scenario, or during 2017 at the latest).

NEXT CATALYSTS

- 3-6th December: Follow-up data from different candidates in a range of haematological malignancies.
- H1 2017: Preliminary data from Cellectis' UCART19 + Novartis's CLT019 filing for approval in paediatric acute lymphoblastic leukaemia.

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Distribution of stock ratings

BUY ratings 72% NEUTRAL ratings 0% SELL ratings 28%

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