Sector View

Biotechnology

JCAR015's safety issues back under the spotlight. Read-across for ALCLS and NVS

	1 M	3 M	6 M 3	31/12/15
Healthcare	-5.6%	-9.4%	-7.3%	-15.8%
DJ Stoxx 600	-1.0%	-0.8%	1.2%	-6.8%
*Stoxy Sector Indices				

Companies co	vered		
ABLYNX		BUY	EUR16
Last Price	EUR8.97	Market Cap.	EUR546m
ADOCIA		BUY	EUR82
Last Price	EUR51.42	Market Cap.	EUR352m
BONE THERA	PEUTICS	BUY	EUR30
Last Price	EUR7.601	Market Cap.	EUR52m
CELLECTIS		BUY	EUR37
Last Price	EUR16.8	Market Cap.	EUR594m
CELYAD		NEUTRAL	EUR21
Last Price	EUR17.655	Market Cap.	EUR164m
DBV TECHNO	LOGIES	BUY	EUR91
Last Price	EUR67.25	Market Cap.	EUR1,621m
ERYTECH		BUY	EUR30
Last Price	EUR13.34	Market Cap.	EUR106m
GALAPAGOS		BUY	EUR64
Last Price	EUR54.91	Market Cap.	EUR2,535m
GENEURO		BUY	EUR18.2
Last Price	EUR7.34	Market Cap.	EUR108m
GENMAB		BUY	DKK1900
Last Price	DKK1251	Market Cap.	DKK75,498m
INNATE PHAR	RMA	BUY	EUR23
Last Price	EUR14.65	Market Cap.	EUR790m
MORPHOSYS		BUY	EUR65
Last Price	EUR46.09	Market Cap.	EUR1,344m
NICOX		No rating	U.R.
Last Price	EUR7.679	Market Cap.	EUR192m
TRANSGENE			EUR5
Last Price	EUR2.61	Market Cap.	EUR147m
ZEALAND		BUY	DKK223
Last Price	DKK126.5	Market Cap.	DKK3,298m

Juno shares fell by more than 25% yesterday following the announcement of a voluntary clinical hold on its ROCKET 2 trial (Phase II evaluating JCAR019, an anti-CD19 CAR-T, in B ALL) following two patient deaths from cerebral oedema. We believe these safety issues are company/product-specific... And consequently, 1/ any pronounced pressure on ALCLS' shares could be an opportunity to revisit the case; 2/ we see a positive read-across for NVS' CTL019 as JCAR015's filing for approval could be further delayed... or even cancelled.

ANALYSIS

- JCAR015's trial once again put on hold due to safety issues. Juno yesterday voluntarily placed on
 hold its ROCKET 2 trial evaluating JCAR015 (CD19 CAR-T) in adults with relapsed/refractory B acute
 lymphoblastic leukaemia following two patients deaths from cerebral oedema earlier this week.
 Obviously, the company is trying to better understand the reasons behind these cases. And once
 done, we'll see if this specific programme will be resumed or even discontinued...
- Towards more scepticism? A few months ago, the FDA put a clinical hold on the very same trial
 because of several patient deaths (also due to severe neurological side effects). Juno explained
 such adverse events could be related to the pre-conditioning regimen (fludarabine +
 cyclophosphamide), and the trial was resumed after a few changes to the trial design. Since then,
 the street has been increasingly worried about this development... and some even wondered if
 such issues are CART-related or not. And unfortunately, this news might provide material for the
 most sceptics.
- A company-specific issue. For our part, we believe these safety issues could be candidate-specific as 1/ no other CAR-T cells have reported similar problems, whether Novartis, Kite or Bellicum... And even Juno apart from JCAR015; 2/ cerebral oedema is one of the adverse events known to be associated with the administration of fludarabine. So any pronounced pressure on ALCLS shares should be seen as an opportunity to revisit the case in our view (especially since key clinical data is to be published in H1 2017). Also, we see a positive read-across for NVS' CTL019 as JCAR015's filing for approval could be further delayed, or even cancelled in a best-case scenario.

VALUATION

We remain at Buy on Cellectis (FV EUR37) while reiterating our neutral stance on Novartis (FV CHF81). But note that CTL019 is quite a small candidate within NVS' portfolio as we foresee peak sales of c.USD400m by 2022.

NEXT CATALYSTS

- H1 2017: Cellectis UCART19 interim Phase I/II data in ALL/CLL (at ASCO for the latest).
- 2017: CLT019 BLA submission in both paediatric ALL and DLBCL.

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Stock rating

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Positive opinion for a stock where we expect a favourable performance in absolute terms over a period of 6 months from the publication of a recommendation. This opinion is based not only on the FV (the potential upside based on valuation), but also takes into account a number of elements that could include a SWOT analysis, momentum, technical aspects or the sector backdrop. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.

NEUTRAL

Opinion recommending not to trade in a stock short-term, neither as a BUYER or a SELLER, due to a specific set of factors. This view is intended to be temporary. It may reflect different situations, but in particular those where a fair value shows no significant potential or where an upcoming binary event constitutes a high-risk that is difficult to quantify. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.

SELL

Negative opinion for a stock where we expect an unfavourable performance in absolute terms over a period of 6 months from the publication of a recommendation. This opinion is based not only on the FV (the potential downside based on valuation), but also takes into account a number of elements that could include a SWOT analysis, momentum, technical aspects or the sector backdrop. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.

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