17th June 2016

Sector View

Pharmaceuticals

Merck reports positive KEYNOTE-024 phase III results in 1L lung cancer

	1 M	3 M	6 M	31/12/15
Healthcare	-1.6%	-1.5%	-10.4%	-12.5%
DJ Stoxx 600	-4.0%	-5.8%	-10.9%	-12.2%

*Stoxx Sector Indices

Companies covered		
ACTELION	BUY	CHF173
ASTRAZENECA	BUY	5100p
BAYER	NEUTRAL	U.R.
GLAXOSMITHKLINE	BUY	1740p
IPSEN	BUY	EUR63
NOVARTIS	NEUTRAL	CHF89
NOVO NORDISK	NEUTRAL	DKK400
ROCHE HOLDING	BUY	CHF293
SANOFI	NEUTRAL	EUR83
SHIRE PLC	BUY	6500p
UCB	NEUTRAL	EUR80

Yesterday, Merck reported that its KEYNOTE-024 phase III trial has achieved both primary and secondary endpoints of PFS and OS. DMC has therefore recommended that the trial be stopped to allow cross-over. This is obviously good news for Merck and Keytruda. Will be the magnitude of the benefit. Note that KEYNOTE-024 recruited only PD-L1 positive patients, hence the limited size of the trial (305 patients) and the indication will therefore be limited to these patients. Roche and AstraZeneca are hoping they can achieve more in combination with chemotherapies, or with other IO agents.

ANALYSIS

- As always, we do not have details, but the KEYNOTE-024 phase III trial that was investigating Keytruda (pembrolizumab) in first-line, non-small-cell lung cancer with high expression of PD-L1 (>50% score) met both its primary and key secondary endpoints of PFS and OS. In monotherapy, the selection of PD-L1 positive patients was a reasonable and cautious option made by the sponsors to increase the probability of success, while keeping the size of the trial low. Hence, it recruited only 305 patients who were split into 6 different groups including pembro 200 mg every three weeks or one of five platinum-based chemotherapy regimens.
- Actually the biggest surprise considering the size of the trial is that PFS was met as evidence is growing that IO agents may not be well designed to show benefit on this criteria while being much more suited for OS benefit. So, although Keytruda in any case will be limited to PD-L1 positive NSCLC patients only and will then require a systematic tumour testing before initiation, it is very likely that it is going to take a major part of this market segment. Results will be compared to Opdivo's in this setting that showed 9.2 months median OS vs 6.0 months for docetaxel in the CHECKMATE-017 trial for instance (squamous NSCLC only). Now it remains to be seen if a direct combination with other agents front-line triggers superior efficacy with reasonable toxicity, in which case standard of care will shift again. First results are expected in 2017 for Roche and AstraZeneca's compounds.

NEXT CATALYSTS

- Today: 1st Oncology Day Bryan Garnier-Institut Curie

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