

Sector View

Pharmaceuticals

	1 M	3 M	6 M	31/12/15
Healthcare	-7.9%	-12.6%	-5.9%	-16.3%
DJ Stoxx 600	-3.4%	-1.2%	-1.2%	-9.4%

*Stoxx Sector Indices

Companies covered

Company	Rating	Price	Market Cap.
ACTELION	NEUTRAL	CHF180	
Last Price		CHF137,1	Market Cap. CHF14,774m
ASTRAZENECA	BUY	5220p	
Last Price		4434,5p	Market Cap. GBP56,098m
BAYER	NEUTRAL	EUR98	
Last Price		EUR88,75	Market Cap. EUR73,392m
GLAXOSMITHKLINE	BUY	1930p	
Last Price		1554p	Market Cap. GBP75,775m
GRIFOLS	NEUTRAL	EUR20	
Last Price		EUR17,655	Market Cap. EUR10,974m
IPSEN	BUY	EUR72	
Last Price		EUR61,32	Market Cap. EUR5,113m
NOVARTIS	NEUTRAL	CHF81	
Last Price		CHF68,95	Market Cap. CHF181,140m
NOVO NORDISK	NEUTRAL	DKK270	
Last Price		DKK236,8	Market Cap. DKK476,575m
ROCHE HOLDING	BUY	CHF285	
Last Price		CHF222,7	Market Cap. CHF156,461m
SANOFI	NEUTRAL	EUR84	
Last Price		EUR72,29	Market Cap. EUR93,191m
SHIRE PLC	BUY	6800p	
Last Price		4539p	Market Cap. GBP41,010m
SOBI	SELL	SEK90	
Last Price		EUR98,2	Market Cap. EUR26,552m
UCB	NEUTRAL	EUR80	
Last Price		EUR59,78	Market Cap. EUR11,628m

Safety issues arise from ACE910's trial... Do not rush to make a judgement

Some patients in ROG's trial evaluating ACE910 have experienced severe thrombotic events. Given yesterday's share price reactions, the Street seems to have taken for granted that such side effects could be associated to the compound. However, it is worth mentioning that these patients were previously treated with bypassing therapies that are known to increase thrombotic risks. We believe the phase III results expected by year-end are likely to bring some answers and as a consequence we reiterate our hierarchy for the haemophilia field.

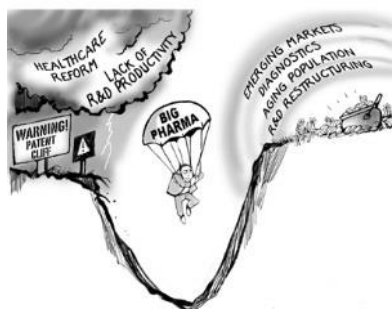
ANALYSIS

- **Severe thrombotic AE seen in ACE910's trial.** Roche revealed that four patients from one of its trial evaluating ACE910 experienced severe thrombotic adverse events (two thromboembolic events and two cases of thrombotic microangiopathy). As a result, the company has issued dear investigator letters (DILs) 1/ to better monitor thrombotic markers, and 2/ to implement further safety measures. As the patients included were said to be previously treated with bypassing therapies (Feiba, NovoSeven), we understand that the trial is the one involving patients who developed inhibitors.
- **Do not rush to make judgement.** Given yesterday's share price reactions, the Street seems to have taken for granted that these side effects are ACE910-related, and especially since the trial involves four active arms testing different doses of this drug without comparative arm. But there is no certainty here in our view as the patients used to be treated with either SHP's Feiba or Novo's NovoSeven, and both of them are known to increase thrombotic risks (Diringer et al, 2008; Aledort et al, 2004).
- **But we still believe ACE910 is unlikely to fully address the whole Haemophilia A market.** Although we would not suddenly bark with the hounds and suggest that ACE910 carries high risk of failure, we remain cautious about the overall safety profile of the drug (severe AEs like appendicitis and mesenteric hematoma being observed in a small phase I; and although they are apparently non-neutralizing ones, some patients developed antibodies against the molecule). No more, no less than we were before and as described in our recent report about Haemophilia. So far, we can just reiterate our belief that FVIII will remain the SOC despite ACE910's competition and thus will remain the standard of care for patients with no inhibitors.
- **First phase III results with ACE910 in patients with inhibitors are expected by year end and are likely to give some answers... As a consequence, we stick to our hierarchy in the haemophilia field.** As a reminder, we foresee peak sales of USD2.0bn for ACE910 (of which USD1.5Bn should stem from patients with inhibitors) although we have so far applied a 40% probability of success, which is severe for a drug in phase III but reflects the risk associated with a mechanism of action. As soon as the first results are out and we will balance PoS and PS accordingly. Compared to our recent report and following disappointing third-quarter figures, note that we have adjusted downwards our numbers on Novo's Haemophilia franchise (DKK2,285m in Q3 vs DKK2,530m in Q2 and DKK2,836m in Q1). We remain more pessimistic than CS about NovoSeven that we see sales halved between 2015 and 2020.

NEXT CATALYSTS

- Q4 16: phase III results of ROG's ACE910 for the treatment of haemophilia A patients with inhibitors.

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BUY ratings 56,7%

NEUTRAL ratings 31,8%

SELL ratings 11,5%

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