20th January 2016

Healthcare

DBV Technologies

Price EUR47.30

FDA's briefing documents favouring EPIT

Fair Value EUR92 (+95%) **BUY**

Bloomberg	DBV FP
Reuters	DBV.PA
12-month High / Low (EUR)	81.0 / 37.8
Market Cap (EURm)	1,140
Avg. 6m daily volume (000)	50.80

	1 M	3 M	6 M	31/12/15
Absolute perf.	-26.7%	-21.0%	-37.0%	-28.8%
Healthcare	-5.6%	-5.4%	-15.1%	-7.4%
DJ Stoxx 600	-7.8%	-8.6%	-17.9%	-9.0%

	2014	2015e	2016e	2017e
P/E	NS	NS	NS	NS
Div yield (%)	NM	NM	NM	NM

ANALYSIS

- The FDA released yesterday briefing documents (please see here) ahead of a panel discussion from the Allergenic Products Advisory Committee on the clinical development and licensure of food allergy immunotherapies scheduled on 21st January. Not only did these documents recognise the Double Blind Placebo-Controlled Food Challenge trial (DBPCFC) as gold standard trial but they also insist on the goal of food allergy immunotherapy, which is the mitigation of symptoms of accidental exposure to allergen as well as close monitoring of patients, which has been undertaken by DBV.
- Moreover, these briefing documents favour DBV's EPIT approach in our view as they highlight the increased safety profile of EPIT compared to either oral immunotherapies (OIT), sublingual immunotherapies (SLIT) or subcutaneous immunotherapies (SCIT). For OIT which is the administration route studied by Aimmune Therapeutics (phase III results in H2 2017), the FDA highlighted the high rate of adverse events (oral and GI side effects), the development EoE which might be induced by the administration of milk protein and more importantly, the risk of this approach in paediatric populations as they might not be able to communicate on early symptoms. This could negatively impact Aimmune in our view as the addressable paediatric population (4-5yo) is made up for 25% of the 4-11yo market and literature shows that early treatment improves responder rate. As for SCIT and SLIT, the regulatory authority spotlighted one fatality case and weak efficacy respectively.
- Lastly we would remind that although the briefing documents do not seem to take into consideration advancements made by DBV in Milk, this is due to the agency's policy not to include results from studies that have not been published in a peer-reviewed journal in its briefing documents issued for open discussion. As such, the FDA refers to the AP-HP trial conducted in 2010 in 19 patients, which showed a positive trend but was not statistically significant.

VALUATION

- We reiterate our EUR92 Fair Value and BUY recommendation

NEXT CATALYSTS

- 4th-7th March: American Academy of Allergy, Asthma & Immunol (AAAAI). Probable communication of the CoFAR6 study results (mechanistic, biomarkers; NIH-sponsored)

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Distribution of stock ratings

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

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