25th November 2016

Healthcare

GlaxoSmithKline

Price 1,523p

GSK brings third HIF-PHI into phase III

Fair Value 1930p (+27%) **BUY**

Bloomberg	GSK LN
Reuters	GSK.L
12-month High / Low (p)	1,723 / 1,280
Market Cap (GBPm)	74,264
Avg. 6m daily volume (000)	9 272

	1 M	3 M	6 M	31/12/15
Absolute perf.	-7.2%	-8.2%	5.4%	10.9%
Healthcare	-4.1%	-8.8%	-8.0%	-15.1%
DJ Stoxx 600	-0.7%	-0.9%	-0.7%	-6.6%

	2015	2016e	2017e	2018e
P/E	20.1x	15.0x	13.0x	12.4x
Div yield (%)	6.6%	5.3%	5.3%	5.8%

ANALYSIS

- Yesterday GSK announced that it was entering phase III with daprodustat, its hypoxia-inducible factor prolyl hydrolase inhibitor (HIF-PHI) to treat anaemia associated with chronic kidney diseases (CKD). The programme will consist of two studies named ASCEND-D in 3,000 patients undergoing dialysis (switching from EPO) and ASCEND-ND in 4,500 non-dialysis dependent patients (switching from EPO or naïve to therapy).
- The class is seen as an interesting one to investigate for the industry because it could offer these patients suffering from life-long diseases a therapeutic option having both the advantage of an oral route (vs weekly injections) but also a more physiological behaviour and a safer profile. Patients with CKD have low levels of EPO and high levels of iron in the body. Current treatments consist of injecting EPO but this is associated with an increased cv risk (MI, stroke, VTE) and a risk of the tumour progressing or recurrence, as reflected into the label with black box warnings. HIF-PHI uses the adaptive function of the human body in low oxygen conditions (like high altitudes), which includes production of oxygen-carrying red blood cells.
- That said, two compounds in the class are already advanced in phase III trials: vadadustat from Akebia Therapeutics (which has been running PRO$_2$TECT in non-dialysis patients for a year and INNO$_2$VATE for a quarter in dialysis patients) and roxadustat from FibroGen, licensed to Astra-Zeneca for the US and China, to Yamanouchi for Japan and to Astellas for Europe and ROW. Roxadustat is expected to deliver final results by year-end for submission in China and is involved in many studies in dialysis and non-dialysis patients most of which delivering data in 2017, leading to a US filing towards the end of 2017.
- Although it is indeed good news to see GSK strengthening its pipeline with a promising compound, third-to-market position is not fully comfortable if there is no differentiating factor. At this stage, differentiation is not obvious to us although GSK emphasized previously efficacy at a very low dose and more importantly ambition well beyond anaemia in CKD patients (DFU, MDS, …). But this is a longer-term story because already in CKD the group is talking about a filing ex-Japan in 2021.

VALUATION

- Given the competitive landscape and the horizon to file, and despite entry in phase III, we have decided to wait until roxadustat delivers first phase III data to decide if we factor daprodustat into our model. As a reminder, even roxadustat (AZN) carries a 20% PoS only.

NEXT CATALYSTS

- 29th November 2016: Vaccines Day in Belgium

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Eric Le Berrigaud, eleberrigaud@bryangarnier.com

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BRYAN, GARNIER & CO

London
Beaufort House
15 St. Botolph Street
London EC3A 7BB
Tel: +44 (0) 207 332 2500
Fax: +44 (0) 207 332 2559
Authorised and regulated by the Financial Conduct Authority (FCA)

Paris
26 Avenue des Champs Elysées
75008 Paris
Tel: +33 (0) 1 56 68 75 00
Fax: +33 (0) 1 56 68 75 01
Regulated by the Financial Conduct Authority (FCA) and the Autorité de Contrôle prudential et de resolution (ACPR)

New York
750 Lexington Avenue
New York, NY 10022
Tel: +1 (0) 212 337 7000
Fax: +1 (0) 212 337 7002
FINRA and SIPC member

Munich
Widenmayerstrasse 29
80538 Munich
Germany
+49 89 2422 62 11

New Delhi
The Imperial Hotel Janpath
New Delhi 110 001
Tel +91 11 4132 6062
+91 98 1111 5119
Fax +91 11 2621 9062

Geneva
rue de Grenus 7
CP 2113
Genève 1, CH 1211
Tel +4122 731 3263
Fax+4122731 3243
Regulated by the FINMA