

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

#### 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<sub>2</sub>TECT in non-dialysis patients for a year and INNO<sub>2</sub>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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