EDISON

Onxeo

R&D news

Livatag's future less clear; Validive finds partner

Pharma & biotech

As announced on Monday evening, the Phase III stage Livatag did not meet the primary endpoint of improving survival in hepatocellular carcinoma (HCC) patients after treatment failure with sorafenib over the comparison arm, where patients received the standard of care (SoC). This morning, Onxeo announced that it had out-licensed its Phase III ready orphan oncology asset Validive to Monopar Therapeutics for a total deal value of $108m and up to double-digit royalties.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14	22.1	0.2	(0.05)	0.0	N/A	N/A
12/15	3.5	(20.0)	(0.44)	0.0	N/A	N/A
12/16	4.4	(20.4)	(0.48)	0.0	N/A	N/A
12/17e	7.8	(21.7)	(0.46)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, share-based payments

Unexpected high survival in the comparison arm was the main reason given by the company for Livatag (innovative formulation of doxorubicin) not meeting the primary endpoint. Onxeo noted that Livatag tended to show a similar level of efficacy as recently approved (April 2017) regorafenib in second line treatment of a subpopulation of HCC patients with well-preserved liver function (inter-trial comparison, not head-to-head data). Onxeo will present the data and subgroup analysis at the International Liver Cancer Association (ILCA), 15-17 September 2017.

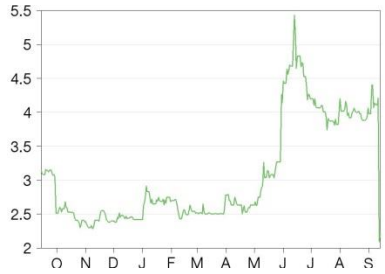
HCC is the fifth most diagnosed cancer globally and the third leading cause of death. Two thirds of patients are usually diagnosed at an advanced stage and so far only two innovative tyrosine kinase inhibitors (sorafenib and regorafenib) have been approved. The unmet need is still significant in this indication; therefore Onxeo expects to explore all options for licensing after the full Phase III results are presented. While this is a setback for Livatag, we await the full data set to see what remaining potential Livatag has before updating our valuation.

Yesterday Onxeo announced more positive news, revealing an exclusive worldwide licensing deal with privately-owned Monopar Therapeutics which will continue the development of Validive (clonidine mucoadhesive buccal tablet for oral mucositis in cancer patients post radiation or chemotherapy). The terms include a $1m in upfront payment, $15.5m for registration (Validive is Phase III ready), and $92.5m in commercial milestones and up to double-digit royalties. Onxeo's intention was to out-license Validive and not to initiate the Phase III trial on its own. Therefore, we had a lower success probability of 50% for the asset to reach the market (reflecting good Phase II data, but a need for partner).

14 September 2017

Price	**€2.19**
Market cap	**€112m**
Net cash (€m) at end-Q217	24.3
Shares in issue	41.4m
Free float	85%
Code	ONXEO
Primary exchange	Euronext Paris
Secondary exchange	OMX Copenhagen

Share price performance



Business description

Onxeo is focused on orphan cancer and has four orphan oncology assets in various stages of development (Livatag, AsiDNA, belinostat and Validive). Royalty-earning Beleodaq (belinostat) is launched in the US, along with two non-core, partnered, specialty products.

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