Evaluate Vantage

June 17, 2015

Synergy relaxes with positive constipation data

Jonathan Gardner

The last major unattached late-stage constipation project, Synergy Pharmaceuticals' plecanatide, today passed a key test with a win in its first phase III trial in patients with chronic idiopathic constipation.

Release of data from the CIC3 study ought to stimulate some discussion with the newly dominant players in the gastrointestinal space, particularly Valeant, as the acquisitive Canadian company does not have an entry in constipation. Plecanatide's equally important irritable bowel syndrome (IBS) trial will not read out until later this year, but the constipation results should increase confidence that this too will be positive.

Competitive

About twice as many patients taking plecanatide as those taking a placebo achieved a durable overall response – 21% in an arm taking 3mg once daily and 19.5% taking 6mg once daily, with 10.2% of placebo patients reaching the study's primary endpoint. Plecanatide patients registered a higher diarrhoea rate – 5.9% and 5.5% in the 3mg and 6mg groups to 1.3% in the placebo arm.

This constipation responder rate is on a par with Linzess, which has the same mechanism of action in guanylate cyclase type-C receptor activation, making it competitive with Allergan's third-biggest seller on efficacy; moreover, plecanatide's diarrhoea rate was lower than the 16% of Linzess. This was a more than satisfactory result for Synergy's investors, who pushed the shares up 47% to a record high of $6.80 in early trading today.

Analysts from Cantor Fitzgerald and Roth Capital Partners reckon that plecanatide could become a blockbuster sometime after 2020, with Cantor forecasting that it will break the billion-dollar worldwide sales threshold in 2022.

But, to get there, effectiveness in chronic idiopathic constipation will need to be confirmed in a second trial, as well as getting positive results in the constipation-predominant IBS indication that could represent a significant share of sales. Chronic idiopathic constipation is not the same disease, but given the mechanism of action and the good safety profile shown today it seems a given that plecanatide's likelihood of success in IBS is now much higher.

And given the size of the market Synergy will need a commercial partner, talks on which are likely to have accelerated given the trial results announced today.

Let's make a deal

This is where Valeant comes in. In its top branded product Xifaxan 550 Valeant has what is forecast to be the biggest-selling drug in the IBS space, but this is for the diarrhoea-predominant form of disease.

In addition to Linzess, rival Allergan has the just-approved Viberzi in diarrhoea-predominant IBS; Valeant stands a chance of dominating this space if it secures plecanatide too (*IBS now an Actavis vs Valeant game, May 28, 2015*).

Valeant did not elbow its way into pharma's top 50 companies by sales by signing a lot of licensing deals, so investors are surely thinking that this positive phase III trigger signals M&A rather than collaboration talks. Indeed, in this frothy biotech market, anything less might be seen as a big disappointment.

Trial	ID
CIC3	NCT01982240

To contact the writer of this story email Jonathan Gardner in London at jonathang@epvantage.com or follow @ByJonGardner on Twitter

More from Evaluate Vantage

Evaluate HQ
44-(0)20-7377-0800

Evaluate Americas
+1-617-573-9450

Evaluate APAC
+81-(0)80-1164-4754