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Auxilium lifted by positive Peyronie’s data

After disappointing sales since its launch in Dupuytren's contracture two years ago, Xiaflex looks to have another chance to prove its worth. Auxilium Pharmaceuticals this week reported positive data in Peyronie’s disease, the growth of scar tissue that can cause a painful curvature of the penis, an indication thought to represent a sales opportunity worth at least $200m a year.

Shares rose 16% to a one-year high of $21.91 following announcement of results on Monday, returning Auxilium to levels last seen before analysts trimmed forecasts in the original indication last summer. Now that expectations are growing again for the collagen-destroying enzyme, the Pennsylvania firm needs to deliver on its promise – positive data could create new possibilities of partnering the drug (Event – Auxilium hopes successful Peyronie’s data is just around the corner, May 23, 2012).

Rounding the bend

The two phase III trials found statistically significant improvements in penile curvature deformity when compared to placebo, with mean improvements of 37.6% in the Impress I trial and 30.5% in the Impress II trial, compared with placebo improvement of 21.3% and 15.2%, respectively. In a call with investors, Auxilium executives noted that all trial participants underwent bending and stretching exercises known as “modelling,” which means the placebo arm was an active one that may not reflect the experience of typical Peyronie’s patients.

Patients in the treatment arm also scored statistically significant improvements on the “bother” domain of an Auxilium-created test called the Peyronie’s disease questionnaire – a test that limited the number of evaluable patients because it excluded patients who had not been sexually active in the preceding three months. The company said that exclusion of those patients from the final measurable study population had been required by the FDA, but it affected both the active treatment and placebo arms roughly equally.

Penile haematomas, pain and swelling were the most common adverse events.

With successful results in hand Auxilium says it will now file a supplementary biologics license application to the FDA by the end of the year, meaning should regulators grant first-pass approval marketing could begin by the end of 2013. Given its approval in Dupuytren’s contracture, a condition involving curvature of fingers resulting from abnormally thickened connective tissues, Xiaflex may not require advisory committee consideration; however, a panel is not out of the question due the novel new use.

Upgrade

Following the announcement, analysts from Leerink Swann raised their price target on Auxilium from $20 to $25, saying the new data increased the probability of regulatory approval from 60% to 80%.

Auxilium estimates that up to 125,000 men a year are diagnosed with Peyronie’s disease although just 5,000 receive injectable or surgical treatment. Given that just 7,500 Dupuytren’s contracture procedures took place in 2011, approval in Peyronie’s would represent a significant expansion if Auxilium can capitalise on it.

Patients in the Impress trials underwent up to eight injections of the enzyme. At the Dupuytren’s contracture price of $3,000 per injection Peyronie’s could generate sales of up to $24,000 a patient. The RBC analysts said Auxilium may want to price the treatment regimen so it does not exceed the costs of surgery, estimated at $10,000, but that it may be necessary to do so in order to make an effective case to payers that the drug should be covered. Thus, the analysts estimate that the sales opportunity is $200-$500m.

Current consensus estimates put Xiaflex sales at $227m in 2018, with a heavily risk adjusted Peyronie’s forecast contributing about 16% to that total, according to EvaluatePharma data. With successful phase III data, those numbers are likely to see upgrades.

The data also could accelerate partnering talks – no doubt a second successful indication would make Xiaflex a much more attractive asset, and given clinical work in frozen shoulder syndrome the drug has a potential for
further expansions.

Given what an underperformer Xiaflex has turned out to be, any change in its fortune will certainly be welcomed, as reflected in share price rises that have continued into a third day today. Given a second chance, Auxilium needs to deliver on its promise - further disappointment will only feed discontent.