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EP Vantage Interview - Nycomed sold on Daxas opportunity

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With physicians impressed by Daxas (roflumilast) the next hurdle for the product will be global drug regulators, who will make their pronouncements next year. Unsurprisingly, one person who is already sold on the drug's attributes is Håkan Björklund, Nycomed's chief executive.

With the private firm making no secret of its desire for a stock market listing, a successful review and launch of Daxas would certainly boost the group's appeal to investors. Speaking to *EP Vantage* at the European Respiratory Society meeting this weekend, Mr Björklund wisely holds back from predicting a hitch-free regulatory process; however he is convinced that the company has a blockbuster product on its hands.

"We're talking about a disease which is the world's fifth largest killer, and is expected to become the third largest killer, patients are not well treated, and there is a lot of room for new treatments. We're coming with an anti-inflammatory which is a once-daily oral tablet, which in itself is a huge step forward because that will possibly have a big impact on compliance.

"There are a lot of reasons to believe it's going to be a big market for Daxas, once it gets there. It is a huge opportunity for us," he says.

Grander ambitions

Still, if rumours are to be believed, Nycomed has even grander ambitions in its sights, in the shape of a bid for Solvay's drugs arm. Reports last week claimed that a €4bn bid is being prepared, a subject that Mr Björklund refused to be drawn on.

If this occurs, an IPO of the much larger group would certainly be well received, catapulting Nycomed up the league tables. Ranked 26th in the world in 2008 on prescription and OTC sales, according to EvaluatePharma, adding Solvay's unit last year would have created a group with $8bn in drug sales. That would imply a ranking position of 18, sitting alongside major European pharma groups like Novo Nordisk and Merck KGaA.

Whilst Mr Björklund refused to comment on the Solvay situation, he did not deny ambitions to become a public company.

"When the market is ready we will go public; we could go public tomorrow if it was only up to Nycomed. But we have no current plans, we are not working towards an IPO, if it will happen in 12, 24 or 36 months I do not know. It will not happen this year that's for sure," he says.

Biggest opportunity

Until the situation over Solvay is clearer, Daxas certainly appears to be Nycomed's biggest project. Regulators' views will help quantify that opportunity more clearly, and second guessing their opinions is always a difficult game, particularly in the US. Mr Björklund concedes that the drug's use may well be restricted to a severe patient population, at least initially, but overall maintains a note of cautious optimism.

Physicians believe that the most likely side effect to raise eyebrows at the FDA will be weight gain, and possibly diarrhoea, and some analysts have speculated that the FDA will require a Risk Evaluation and Mitigation Strategy (REMS), as is becoming increasingly the norm. An advisory panel is certain to be called to evaluate the drug, given it would be the first in its class to reach the market for COPD.

"We're very optimistic about the regulatory outcome, but you should not speculate ahead of time," Mr Björklund says. "No question the FDA has become more and more careful and are demanding more and more data upfront before approval, and post marketing. That's something we have to live with."

As *EP Vantage* also discusses today, as well as side effect issues, regulators are also going to look closely at who should receive the drug (*Vantage Point - Daxas finds fans amongst doctors at ERS, September 14, 2009*). Still, the fact that patients who were using long acting bronchodilators still achieved a meaningful improvement in lung function, as shown in the two six-month trials, could be enough to convince on the

efficacy side.

Broader potential

Mr Björklund said although further trials will certainly be undertaken in an attempt to establish Daxas' potential more clearly, what they will look like has not yet been decided, and probably will not until early next year.

“The data is fairly fresh, but it is also important to have comments from the regulator, what are the issues they would like to see elucidated, but also get feedback from physicians,” he says.

Physcians presenting the results for Nycomed said they would like to see trials investigating whether the drug can improve mortality or improve lung function over time, which would establish whether Daxas has a disease modifying impact. Establishing this in the clinic would require long and costly trials, but if successful would be hugely important commercially for both Nycomed and US commercial partner Forest Laboratories.

A smooth passage in front of regulators would no doubt make the decision about whether to commit to such a study easier to make. However, in the meantime both Nycomed and Forest are no doubt keen to focus on the most important hurdle for the future, getting the drug on the market in the first place.