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Flutiform delay no surprise, but a grim outcome

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Although it came as no surprise, news that SkyePharma's lead drug, the inhaled asthma treatment Flutiform, will not be launched in the US until 2012 must raise doubts about the future of the drug and the company.

Yesterday, SkyePharma announced that FDA had provided a complete response letter confirming what the company already knew; that signficant additional clinical work will be necessary before the US regulators will approve the combination LABA/corticoid treatment. However, with partner Abbott Laboratories contracted to shoulder the cost of additional trials, the US group could decide that it might be time to pull the plug on its investment and hand the rights back to SkyePharma.

Relative impact

Losing Flutiform would not be a massive setback for Abbott, a look at the group's respiratrory frachise shows a rather thin pipeline, with respiratory sales forecast to hit $80m in 2010, according to data from *EvaluatePharma.*Compare this with group sales of $15.9bn that the group is forecast to report this year and a no-go decision on Flutiform will hardly keep executives awake at night. Abbott inherited the project when it bought Kos Pharmaceuticals in 2006, a deal designed to beef up its cardiovascular franchise.

However, for SkyePharma, this latest set back to Flutiform's long and torturous path to US approval, although expected thanks to a regulatory update from the company in their November results, is potentially much more damaging. Shares in the company have fallen 19% to 75p since the announcement yesterday afternoon.

Tough nut to crack

Asthma treatments are set to remain one of the biggest markets in healthcare and royalties from even a small fraction of these sales can mean a big payday for a little company like SkyePharma. However, the FDA stance highlights that getting approval for drugs in this therapy area has become a regulatory minefield, due to the large patient populations, the complications of dosing combined compounds in an inhalation device and past safety scares, all of which mean a very high bar for approval. The company has conducted a staggering six phase III trials with Flutiform, but still this is not enough.

Indeed if anything Flutiform's troubles confirm the words of Andrew Witty, chief executive of Advair manufacturer GlaxoSmithKline, who last week said he did not expect much immediate generic competition to Advair when its patent expires next year, largely because of these regulatory difficulties (*Glaxo banking on Advair longevity, January 14, 2010*). The travails of another LABA/corticoid combination therapy must make Mr Witty more certain of the position of his top-selling drug.

In announcing the further delays SkyePharma put on a brave face by emphasising that it remains on track for submitting an application for European approval in the first quarter, as well as completing a phase II trial in Japan.

The path forward in the US is unlikely to be so smooth. Under the Flutiform licensing deal Abbott must pay for any additional trials required by the FDA, although it is entitled to recoup theses costs out of up to 25% of future milestones and royalties.

For a company with very little respiratory focus, it could well decide that this headache not worth pursuing.

So while a 2012 launch may be a grim assessment for a drug with promise, it could easily get worse for Flutiform, and SkyePharma.

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