Evaluate Vantage

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FDA tampers with Acurox’s approval date

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The announcement that the FDA will miss the June 30 PDUFA date of Acura Pharmaceuticals and King Pharmaceuticals' abuse-resistant instant release opioid drug, Acurox, may have sent shares in Acura down by 22% yesterday, but it was always a possibility given the US regulator's current deliberations over how to prevent the abuse of opioid drugs.

While Acurox is an instant release (IR) abuse-resistant product, and to date the US regulator has focused all of its attention on the extended release (ER) part of the market, concerns about abuse of all opioid products could mean that questions about the appropriate information to put on the label have extended the review.

Even taking into account the ultra cautious FDA, many analysts covering the company had predicted that it was unlikely that Acurox would get past the regulator first time round. Investors, however, looked to have ignored these warnings about the drug’s slim chances of approval, and the shares had crept up over the course of this year and hit an 11-month high of $8.51m earlier in June.

Excessive fall

Although the share price fall looks over done with shareholders on this occasion being harsh in their punishment of Acura, the group’s fate is linked almost entirely to the drug, which is licensed to King Pharmaceuticals and Acura’s only clinical product. With no other clinical stage pipeline candidates to act as a cushion any news on Acurox will have an impact on the share price. Today, the stock was back up by 3% to $6.05 in early trading.

Acurox was licensed to King Pharmaceuticals in October 2007 as part of a three product deal for tamper resistant opioid drugs and is forecast to have sales of $111m by 2014, although this figure may now fall. The drug is based on Acura’s proprietary Aversion Technology platform, which combines niacin with oxycodone, to produce the unpleasant sensation of hot flushes if a person has excessive doses of drug. The company claims this has the benefit of deterring all methods of opioid abuse, including the most difficult to counter, excess pill taking.

Regulatory loophole

When a new PDUFA date is decided for Acura, what the drug has on its side is that as an IR product it is not subject to the tough risk evaluation and mitigation strategies (REMS) that the FDA has decided all marketed ER opioid drugs must have in place.

In February, the agency wrote to 16 manufacturers of opioid products asking them to come up with REMS to reduce risks and ensure that patients with legitimate need for the drugs would continue to have appropriate access. The measures stem from the high incidence of abuse of drugs such as OxyContin.

Without the need for an REMS Acurox could have a new PDUFA date of the end of the year and theoretically be on the market by the first quarter of 2010, making it the first tamper proof IR drug on the market.

However, the worry is that the FDA’s current focus on ER products could simply shift the abuse problem to the largely generic IR end of the market, meaning the regulator may in time be forced to consider requesting IR drugs to have REMS in place as well. This means that any new drugs in development may not face such a relatively simple path to approval.

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