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**Oxecta FDA approval tempered by lack of abuse resistance claim**

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Acura’s ostensibly abuse-resistant formulation of oxycodone, Oxecta, got approval from FDA but with a disappointment on the label: it includes an explicit statement that the pill does not in fact reduce the danger of abuse. Combined with the agency’s call for partner Pfizer to conduct an epidemiological study of whether the new formulation of the pain reliever deters abuse, Oxecta is looking to be a drug with a limited marketing edge for now.

Acura investors initially took some heart in the approval, and the $20m milestone from Pfizer that came with it, by driving shares up 75% to $6.80 soon after market opening yesterday. However, the stock quickly fell back to $4.50 at close, just a 16% gain, and so far have declined a further 9% in early trade today to $4.08 - no tangible net gain compared to last week’s prices. The tempering of investor optimism reflects an understanding that unless Pfizer’s post-approval trial can prove that Oxecta reduces misuse, partnership income will be restricted.

‘No evidence’

Oxecta, formerly known as Acurox, is an immediate-release reformulation of the opioid oxycodone designed to cut abuse by making it difficult to crush and inject or snort. When crushed in a liquid, Oxecta forms a thick gel that is difficult to draw into a syringe, and when inhaled it irritates the nasal passages (Event - Acura and Pain hoping luck will change, May 17, 2011).

As originally submitted, the product included niacin to induce flushing if too many pills were swallowed, but that strategy has been dropped because the niacin could affect people taking therapeutic amounts and because the flushing can be counteracted by food or aspirin (Acura’s blushes cause it to lose adcom backing, April 23, 2010).

The FDA did not buy the company’s latest pitch that its technology does deter abuse; as proved yesterday, the product information states that Oxecta can be abused. It adds: “There is no evidence that Oxecta has a reduced abuse liability compared to immediate-release oxycodone.”

In an accompanying regulatory filing, Acura disclosed that Pfizer will be conducting the post-approval study. Presumably, if the findings of such an study are positive the company can file for a label amendment, but for now it seems Pfizer's salesforce will be restricted in promoting a product that appears to have little differentiation from a pill widely available from generic manufacturers.

At most, the label states that it is “not amenable” to crushing and dissolution so it should not be used in feeding tubes, which could be read as a sign of its anti-abuse characteristics. Whether pain specialists will view it as such or have any other knowledge of the Acura aversion technology is a question that can only be answered once early Oxecta sales numbers come in.

**Readthrough**

There was positive readthrough for Pain Therapeutics on the news; shares in the company that awaits its own FDA approval target date Thursday on pain reliever Remoxy gained 4% to $8.99. Shares in Durect, from whom Pain licensed the high-viscosity sustained-release technology that makes Remoxy resistant to crushing and water extraction, rose 6% to $2.95.

Remoxy is also licensed to Pfizer – which like Oxecta came into the New York group’s portfolio with the acquisition of King Pharmaceuticals – and is forecast as the bigger of the two drugs. EvaluatePharma’s consensus forecast puts 2016 sales of Acurox at $63m, a fraction of Remoxy’s $229m.

Approval for Oxecta suggests a ‘yes’ for Remoxy this week, although the FDA’s stance excluding an abuse-resistance claim on Oxecta may not augur well for Remoxy.
The companies have attempted to support Remoxy’s abuse-resistance claim by supplying data that shows that patients who took Remoxy whole or chewed had significantly lower “drug liking” than those who consumed regular oxycodone whole or crushed. In addition, the time to peak drug liking for Remoxy chewed was significantly delayed compared with crushed oxycodone. It is not a given that the FDA would accept this as compelling evidence - the finding is not dissimilar to a study conducted on Oxecta with niacin.

Whilst public health leaders have been adamant about the need to reduce the abuse of opioid pain medications, the FDA is showing itself to be tough on abuse resistance claims. Acura got its approval but without the resistance claim, so Pfizer, Pain and Durect will be hoping for a more favourable hearing from the regulator.