

## Breaking News on Pharmaceutical Technology

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### Durect ramps up Remoxy manufacturing

By Gareth Macdonald

28/05/2008- **Specialty pharmaceutical firm Durect has begun manufacturing the key components of Remoxy, ahead of a planned NDA filing.**

Remoxy is a long-acting version of the painkiller oxycodone that is based on Durect's Oradur gel-cap sustained release technology. The system employs a gelatin capsule that uses a high-viscosity base component, sucrose acetate isobutyrate (SAIB), to control the release of drug's active ingredient over a period of 12 to 24 hours.

Remoxy is intended to provide the estimated 1.7m chronic pain sufferers in the US with a twice-daily dose of the extended-release oxycodone in a formulation that has reduced abuse potential. The firm estimates that the extended-release oxycodone market is worth around \$1.7bn a year.

Earlier this week, members of an Food and Drug Administration (FDA) advisory panel expressed some concerns during a review of a new formulation of Purdue Pharma's rival abuse resistant product, OxyContin. Some member of the committee, which was not asked to formally decide whether or not to recommend approval, said that branding the product as 'abuse-resistant' may imply that it completely safe.

Durect said that it is ramping up manufacturing of Remoxy to ensure it has sufficient inventories. Speaking at the firm's first quarter earnings call, company CEO Jim Brown said that Pain Therapeutics, its Remoxy development partner, is expected to file a New Drug Application with the FDA before the end of the second quarter.

#### Competition heats up in the anti-abuse market

In March, IntelliPharmaCeutics announced that it is ready to move ahead with full-scale clinical trials of a once-daily oral formulation of oxycodone based on the company's ReXista abuse- and alcohol-resistant technology.

The Canadian drug delivery specialist said that it has successfully completed a pilot clinical study with its controlled-release version of oxycodone, which demonstrated that the ReXista formulation of oxycodone was bioequivalent in a single dose to two doses of the reference drug Oxycontin.

Similarly to Remoxy, ReXista is designed to resist abuse by oral ingestion when the drug is crushed or chewed, by injection when it is combined with solvents or by nasal application when oxycodone is crushed or powdered.

In contrast to Remoxy however, the product has also been developed to prevent the entire daily dose of oxycodone being released when the drug is taken with alcohol *in any quantity*.

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