



Feature
Article

This Month's Features



QRxPHARMA MOVING RAPIDLY WITH FIRST PATIENTS ENROLLED IN PHASE III CLINICAL TRIAL PROGRAMME FOR ITS "DUAL OPIOID" PAIN THERAPY

QRxPharma has announced that a number of patients have been treated in the first of several clinical studies to be conducted as part of the Phase III development programme for its lead product candidate Q8003IR, an immediate release dual-opioid therapy.

The study is being conducted at 8 US clinical research sites and is targeted to enroll 250 patients experiencing moderate to severe pain following a scheduled surgical procedure (bunionectomy).

"Initiation of this Phase III clinical trial programme not only demonstrates the company's ability to deliver on its development milestones for Q8003IR in terms of budget and time line projections, but also represents a significant step forward towards our goal of commercialising our first dual-opioid pain therapy in 2010," said Dr. John Holaday, Managing Director and CEO of QRxPharma Ltd.

The primary clinical endpoints for this acute, post surgery pain study focus on pain relief and pain intensity scores versus placebo over the first 48 hours, post-surgery. Secondary endpoints include; 1/ efficacy relating to the time to onset of analgesia and the duration of effect from a single oral dose; and 2/ safety as measured by the incidence and intensity of opioid-related adverse events.

A safety extension trial will immediately follow patient enrollment in this first trial to begin capturing longer-term patient safety data in support of the company's planned future FDA New Drug Application data submission for Q8003IR.

Q8003IR is a patent-protected, immediate release dual-opioid product that synergistically combines sub-analgesic doses of oxycodone and morphine. Several clinical trials to date have shown that this unique, dual-opioid combination can achieve equal or better analgesic pain relief at materially lower doses than the active opioid comparator while simultaneously reducing side effects (eg. less nausea, vomiting, constipation).

"We are pleased with the progress made to date with our lead product, Q8003IR. It represents the first of several pain products we are developing to leverage the unique clinical benefits of our dual opioid technology," said Doug Saltel, Chief Operating Officer of QRxPharma.

"The moderate to severe pain market in the US is extremely large and well defined, with a relatively small number of specialist physicians accounting for a significant proportion of prescriptions. As a specialty pharmaceutical company, this will allow QRxPharma to effectively target these key prescribing physicians in a very efficient manner," said Mr. Saltel. He further stated: "We have the team and the funds available today to bring Q8003IR through a New Drug Application filing in the US, with the flexibility to launch products ourselves or work with a partner to pursue even greater sales potential."

"As our dual opioid formulations are anticipated to provide superior treatment for acute and chronic pain with fewer side effects, we have a unique opportunity to make a significant difference in people's lives as well as benefit our shareholders," Dr Holaday

concluded.

For the first time, a dollar value has been attached to the high cost of pain in Australia; in an MBF Foundation funded study that reveals a massive annual cost of \$34.3 billion....nearly \$11,000 for each of the estimated 3.2 million people grappling with pain.

The tag price of pain includes both financial costs and loss of healthy life. QRxPharma plans to launch its dual opioid products in Australia to address this significant need.

November 2007

Article by The Australian Investor <http://www.australianinvestor.com.au/>