ASX RELEASE
29 June 2011

QRxPharma Releases Additional Data on Phase 3 Comparative Safety Study for MoxDuo® IR

More comprehensive statistical analysis shows MoxDuo IR, at equi-analgesic doses to either Morphine or Oxycodone, produced significantly less severe respiratory depression

Sydney, Australia and Bedminster, New Jersey -- QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the release of additional data on its Phase 3 safety study for MoxDuo IR. Study 022 compared the respiratory effects of MoxDuo IR to equi-analgesic doses of either morphine or oxycodone in 375 patients experiencing moderate to severe postoperative pain following bunionectomy surgery at 4 US clinical research sites.

A more comprehensive statistical analysis has now been completed that highlights an important clinical advantage of MoxDuo with respect to respiratory depression. In Study 022, respiratory impairment in these patient groups was measured by decreases in blood oxygen levels from the healthy normal range of 96-100% seen at baseline prior to the start of dosing. Oxygen values below 90% (a "desaturation" of hemoglobin) are usually considered clinically significant, and it is widely accepted that the greater the decline in blood oxygen saturation levels and the longer the desaturation lasts, the more severe the clinical outcome if no therapeutic intervention occurs.

To further evaluate such oxygen desaturation, the Company analysed data from patients experiencing the worst (10th percentile) of all observed desaturations. The results demonstrated that the risk of the occurrence of such potentially dangerous desaturations was significantly greater in patients receiving morphine ($p<0.009$) or oxycodone ($p<0.002$) alone than in those receiving MoxDuo. Such desaturations occurred in 12% of the morphine, 15% of the oxycodone and 3% of the MoxDuo treated patients. These findings translate to a relative risk ratio of approximately 4:1 or 5:1 for the either morphine or oxycodone vs. MoxDuo.

"Respiratory depression is the leading cause of death from opioid treatment. Our breakthrough results indicate that MoxDuo provides a significant safety benefit with less clinical respiratory risk than either morphine or oxycodone." said Dr. John Holaday, Managing Director and CEO.

The Company employed a state-of-the-art methodology for capturing the occurrences of oxygen desaturations – the primary study endpoint. Blood oxygen concentration was obtained electronically every 2 seconds from each patient over the 48 hr. study treatment period. This electronic recording process allowed for precise, quantifiable assessments of both the magnitude and duration of respiratory differences among patients receiving doses of MoxDuo, morphine or oxycodone.

"This superior respiratory safety profile for MoxDuo was shown in a study in which both young and old subjects participated," said Holaday. "We believe that such results provide strong evidence to both regulatory agencies and the medical community that MoxDuo is a safer analgesic alternative."

A more detailed analysis of Study 022 with respect to respiratory depression is provided in the attached supplement to this market release.

It should also be noted that unlike earlier MoxDuo studies, Study 022 included a number of FDA-suggested study design elements to explore their utility in seeking one or more comparative label claims. One FDA recommendation required the administration of anti-nausea rescue medication only to patients that vomited and not to those only exhibiting nausea. This significantly limited the interpretation and comparative value of nausea and vomiting measurements and was not in keeping with normal clinical practice. Nonetheless, the occurrence rate of moderate to severe vomiting was significantly ($p<0.04$) reduced (32% vs. 42%) in MoxDuo IR treated subjects compared to patients receiving oxycodone alone at the same 24 mg morphine equivalent dose.

The Company remains on track to file its New Drug Application (NDA) for MoxDuo IR with the United States Food and Drug Administration (FDA) in August 2011. The European Marketing Authorisation Application (MAA) is scheduled for submission in the first half of 2012. MoxDuo is a patented 3:2 ratio fixed dose combination of morphine and oxycodone that targets the acute pain market, a $2+ billion segment of the $8 billion spent annually on prescription opioids in the US.

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About QRxPharma

QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) is a clinical-stage specialty pharmaceutical company focused on the development and commercialisation of new treatments for pain management and central nervous system (CNS) disorders. Based on a development strategy that focuses on enhancing and expanding the clinical utility of currently marketed compounds, the Company's product portfolio includes both late and early stage clinical drug candidates with the potential for reduced risk, abbreviated development paths, and improved patient outcomes. The Company intends to co-promote its products in the U.S. and seeks strategic partnerships for worldwide markets. QRxPharma's lead product candidate, immediate release MoxDuo, has successfully completed pivotal Phase 3 studies and the Company expects to file its New Drug Application (NDA) with the US Food and Drug Administration (FDA) in August 2011. The Company's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MoxDuo, as well as other technologies in the fields of pain management, neurodegenerative disease and venomics.
For more information, visit www.qrxpharma.com.

Forward Looking Statements

This release contains forward-looking statements. Forward-looking statements are statements that are not historical facts; they include statements about our beliefs and expectations. Any statement in this release that states our intentions, beliefs, expectations or predictions (and the assumptions underlying them) is a forward-looking statement. These statements are based on plans, estimates and projections as they are currently available to the management of QRxPharma. Forward-looking statements therefore speak only as of the date they are made, and we undertake no obligation to update publicly any of them in light of new information or future events. By their very nature, forward-looking statements involve risks and uncertainties. A number of important factors could therefore cause actual results to differ materially from those contained in any forward-looking statement. Such factors include risks relating to the stage of products under development; uncertainties relating to clinical trials; dependence on third parties; future capital needs; and risks relating to the commercialisation of the Company's proposed products.

Phase 3 Comparative Safety Study for MoxDuo® IR - Study 022
Supplement to Market Releases 14 June 2011 and 29 June 2011

On 14 June 2011 QRxPharma Limited announced the top line results of Study 022, a Phase 3 study comparing the tolerability and safety profile of MoxDuo IR (a patented capsule combination of morphine and oxycodone) to equi-analgesic doses of either morphine or oxycodone alone. Further results were announced on 29 June 2011 and this document provides a supplement to these two market releases.

Study 022 was a double-blind, randomised, fixed dose trial that enrolled 375 patients with moderate to severe post-operative pain following bunionectomy surgery at four US clinical research sites. Patients received equi-analgesic doses of opioid once every 6 hours – MoxDuo IR 12 mg/8 mg, morphine 24 mg or oxycodone 16 mg.

The primary objective of Study 022 was:

> **"to explore, as the primary end point, the performance of MoxDuo IR relative to morphine and oxycodone comparators with respect to oxygen desaturation, a direct measure of respiratory depression"**

Results of these safety outcomes are intended to support the European Marketing Authorisation Application (MAA) and to be submitted to the Unites States Food and Drug Administration (FDA) as a safety update after the August 2011 NDA filing.

The main objective of the study was met, with valuable information gained that will allow the design of future studies aimed at securing a comparative label claim for the respiratory advantages of MoxDuo IR. This supplement looks in more detail at the findings of Study 022 with respect to the safety of MoxDuo IR in respiratory function – a new and important advantage for MoxDuo.

RESPIRATORY DEPRESSION

Respiratory depression is the leading cause of death from high doses of opioids and is the most serious of opioid-related adverse events. The risk of respiratory depression is increased in elderly or debilitated patients, usually following large initial doses in persons who have not developed any degree of tolerance to the respiratory depressive effects of opioid agonists, or when opioids are given in conjunction with other agents that depress respiratory drive. At therapeutic doses, opioid induced respiratory impairment, either as a result of a slow respiration rate or shallow breathing, places patients at higher risk of asphyxia, experiencing a

stroke, myocardial infarction or cognitive impairment due to periods of low blood oxygen (hypoxia). While severe respiratory impairment with opioids is not common, the risk of this serious and potentially lethal side effect is among the most important considerations in the risk:benefit evaluation of opioid analgesics. In Study 022 the extent of respiratory impairment was measured by decreases in blood oxygen levels from the healthy normal range of 96-100% seen at baseline before dosing. Values below 90% (a "desaturation") are usually considered clinically significant. It is also widely accepted that the greater the decline in blood oxygen saturation levels and the longer the desaturation lasts, the more severe the clinical outcome if no therapeutic intervention occurs to end the desaturation.

The most comprehensive measure of desaturations in a given patient is the "area under the curve" (AUC) of all the desaturations that occurred. The AUC of an individual desaturation episode is the duration of the desaturation (seconds) multiplied by the magnitude of the desaturation (decrease below 90% blood oxygen levels). Other measures of desaturation episodes include the duration, the average intensity value, the worst intensity score and the number of desaturations. The AUC of the oxygen desaturations includes the information contained in all of these component measures, and is thus the most comprehensive index available for patients who experience one or more desaturations. The risk of such desaturations occurring is based on the percentage of patients in each treatment group that report one or more desaturations of a given magnitude.

Study 022 employed a sophisticated and relatively new methodology for recording the occurrences of desaturations. A Masimo® pulse oximeter using a finger-tip sensor was used to continuously electronically record the blood oxygen concentration (oxygen saturation level, measured as a percentage of hemoglobin containing oxygen, i.e., SpO2%) every two seconds for each patient over the 48 hour study treatment period, allowing for precise detection and quantifiable assessments of the extent and severity of any desaturations.

OXYGEN DESATURATION AREA UNDER THE CURVE

Key Finding: The respiratory safety data from Study 022 demonstrated substantially superior performance of MoxDuo treated subjects at equi-analgesic doses compared to morphine and to oxycodone when looking at the most serious desaturation AUCs , as well as the total AUC desaturations over the 48 hour dosing period.

As shown in Figure 1, the median AUC of each individual desaturation for the MoxDuo patients were 20% to 45% smaller than those of morphine alone and oxycodone alone, with the latter difference being statistically significant (p=0.018).

Fig 1 – Median Desaturation AUC Values

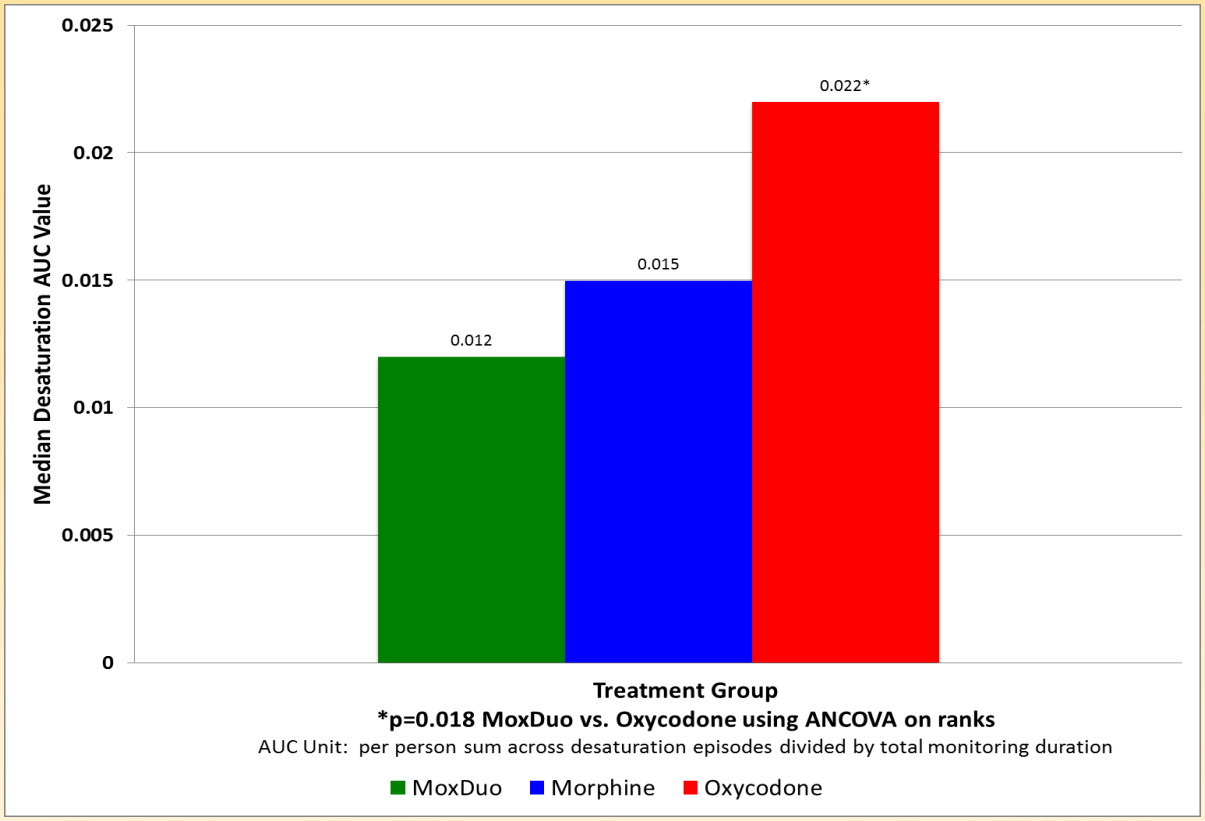


Figure 2 shows the distribution of all of the individual desaturation AUCs, while Figure 3 highlights the 25 percentiles with the worst AUCs.

Fig 2 – Area Under the Curve (AUC)
(Distribution of All Desaturations)

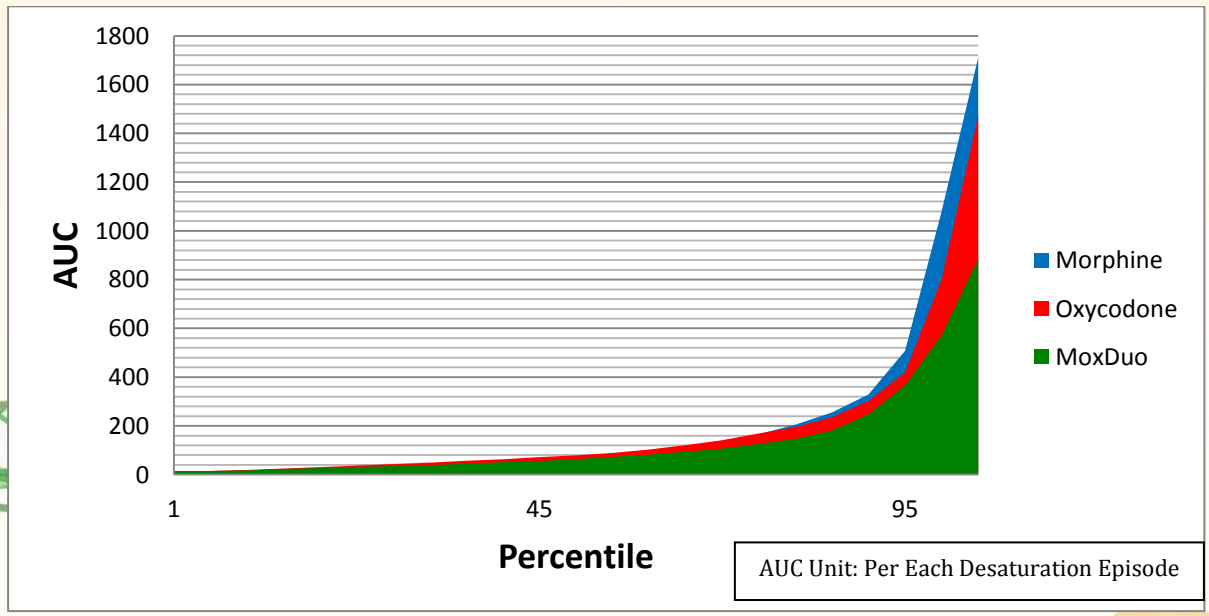
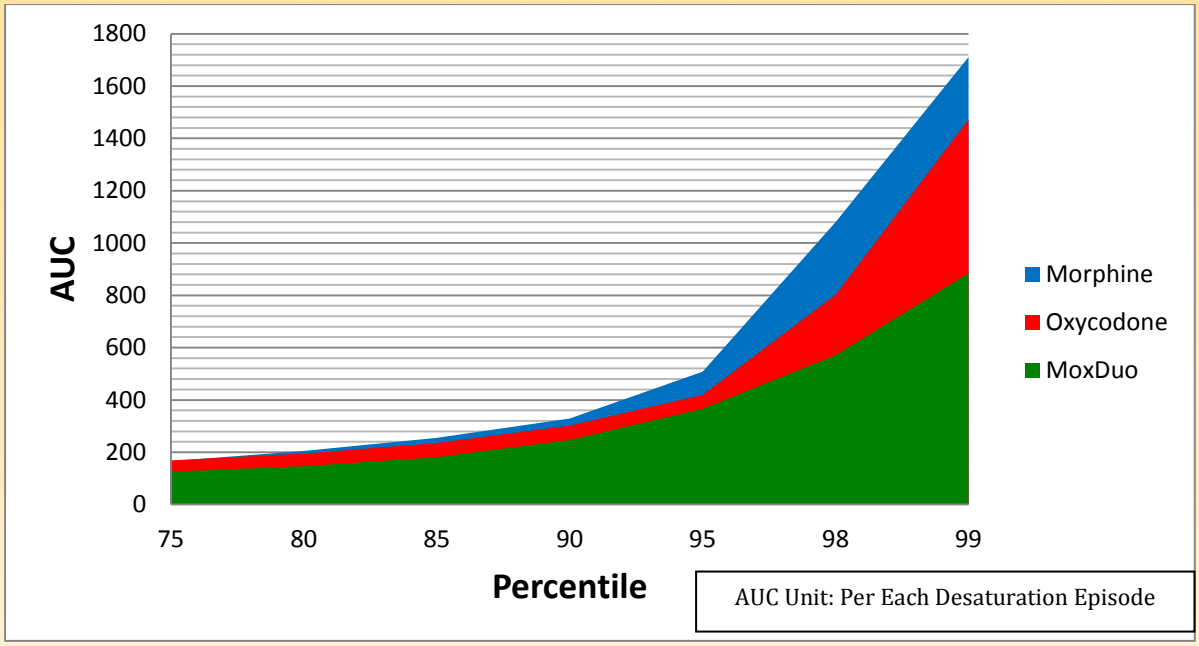


Fig 3 – Area Under the Curve (AUC)
(Most severe episodes)



The area under the curve of the individual desaturations is calculated by multiplying the desaturation intensities (decrease from the 90% SpO_2 level) by the duration (seconds) of the desaturation episode. Results are then expressed either as the sum of the desaturation episodes per patient or as the individual episode values. In essence, the AUC is a measure of the magnitude and duration of a continuous desaturation episode, thus incorporating the desaturation features illustrated in Figures 4 and 5. The results show that there are many more extreme desaturations in the morphine and the oxycodone control groups than in the MoxDuo treated subjects. For the top 1% (worst) desaturation AUC values, the MoxDuo AUCs were 40-48% less than that of the oxycodone and morphine controls, respectively. For the worst 10% of the oxygen desaturation AUCs, the MoxDuo values were 18-25% less than that of the control groups.

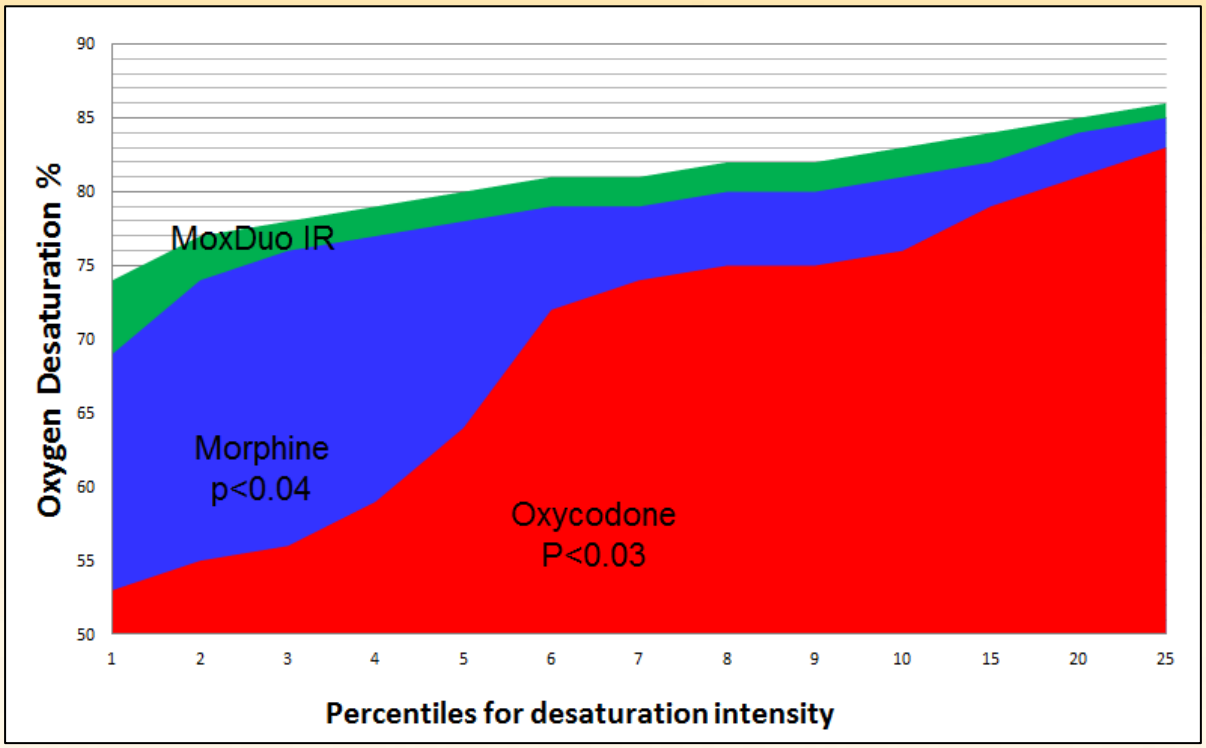
An examination of the worst 10% of all desaturation AUC values observed in the study found that the risk of having such desaturations was significantly greater in patients receiving morphine ($p<0.009$) or oxycodone ($p<0.002$) than MoxDuo IR. Such medically significant desaturations occurred in 12% of morphine, 15% of oxycodone and 3% of MoxDuo IR treated patients, providing a relative risk ratio of approximately 4:1 or 5:1 for the other opioids vs. MoxDuo IR. There were no notable differences in the patient demographics or disposition between the groups in the study. Also, about 40% of patients in both treatment groups were age 60 years or older, an age group that is at enhanced risk of opioid induced respiratory impairment.

INTENSITY, DURATION AND FREQUENCY OF DESATURATION EPISODES

Graphical representations of two important measures of desaturation are provided below:

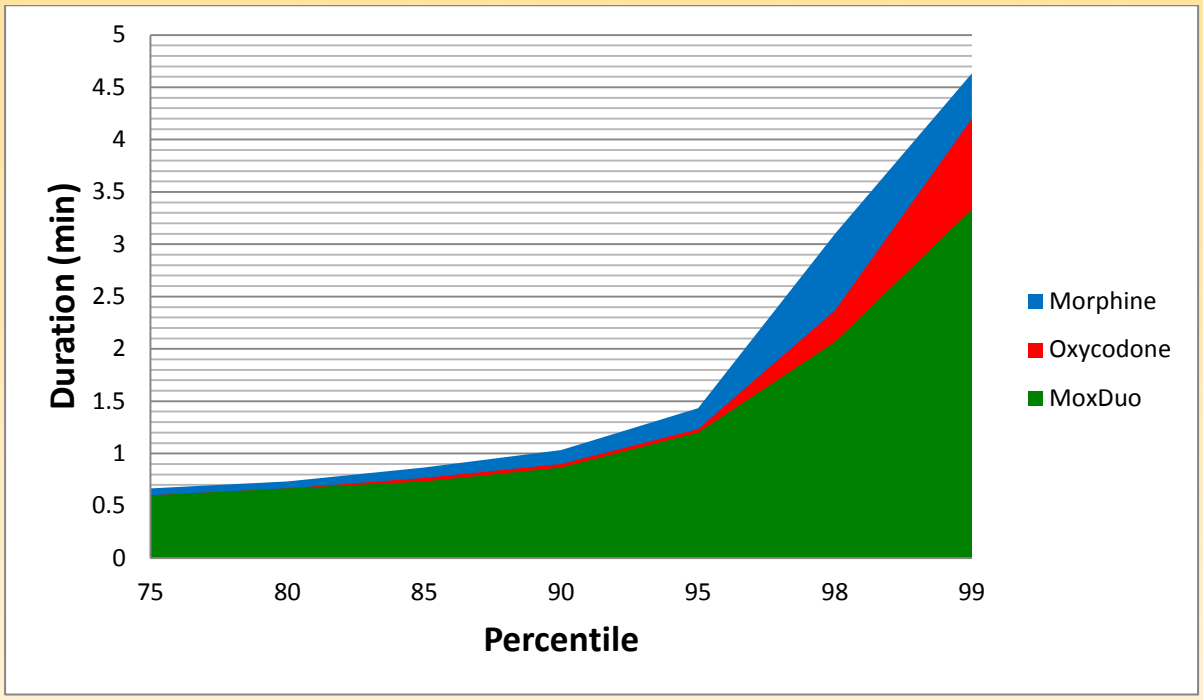
- The **intensity** of desaturation event ranked by percentile (measured by blood oxygen saturation level, see Fig 4)
- The **duration** of desaturation event ranked by percentile (measured in minutes, see Fig 5)

Fig 4 – Distribution of Individual Blood Oxygen Desaturation Intensities (SpO_2%) by Treatment (Worst 25 Percentiles)



Desaturation <u>intensity</u> key findings: The mean intensity of the worst SpO_2 value of the desaturations for a given patient showed MoxDuo events being slightly less intense than morphine or oxycodone treatments (mean SpO_2=83.6%, 82.7% and 82.9% respectively). However, when one evaluates the more extreme desaturations, Figure 4 above shows that MoxDuo patients had significantly less severe desaturations than morphine or oxycodone. For example, the worst 1% of the blood oxygen levels for oxycodone treated subjects had a value of 53%. For morphine the worst 1% of the desaturations had a SpO_2 value of 68% and the worst MoxDuo 1% worst scores had a value of 74%. For the worst 5% of the SpO_2 desaturations, the oxycodone, morphine and MoxDuo values were about 64%, 77% and 80%, respectively. This demonstrates that treatment with oxycodone or with morphine is associated with more intense desaturations than MoxDuo.

Fig 5 – Distribution of Individual Blood Oxygen Desaturation Durations (min.) by Treatment (Worst 25 Percentiles)



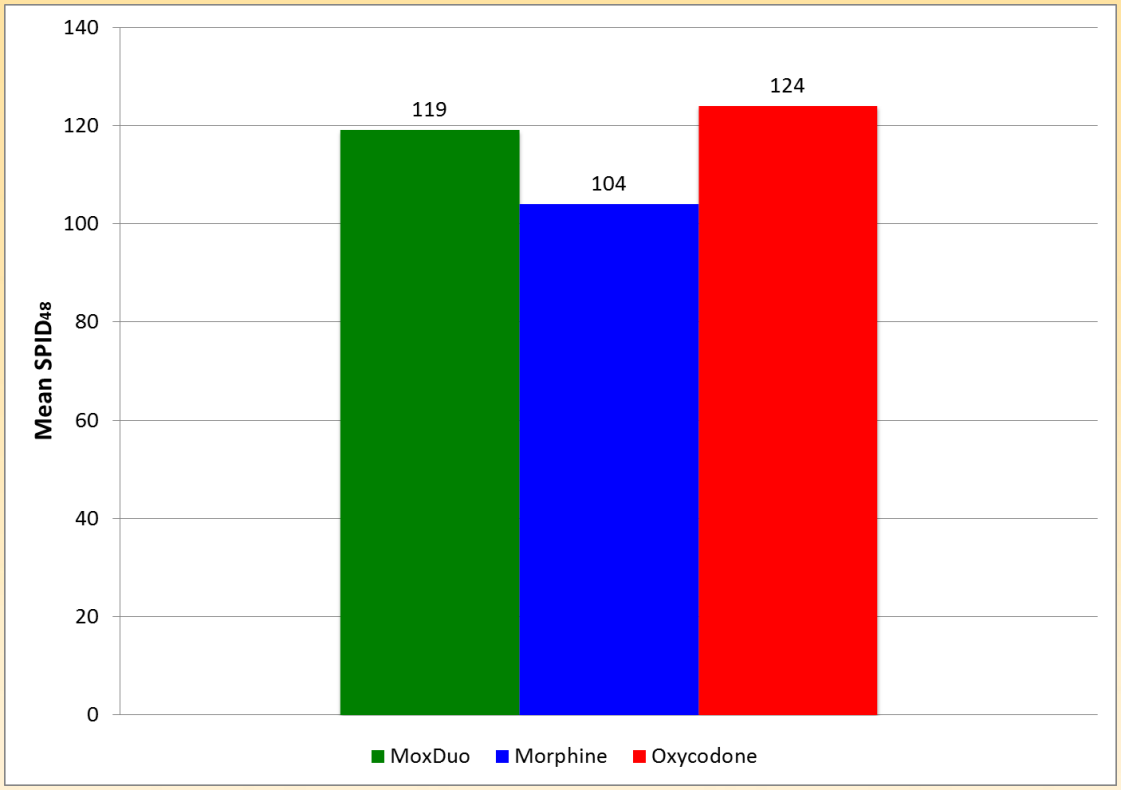
Desaturation <u>duration</u> key findings: The average duration of desaturation events in the MoxDuo IR group (0.7 minutes, range 0.3-3.9 minutes) was shorter than that of morphine (mean 0.9 minutes, range 0.3-23.6 minutes) or oxycodone (mean=0.8 minutes, range 0.3-12.3 minutes), but the differences were not statistically significant. This is not surprising since the study staff were instructed to abort desaturations as soon as they were detected, either by arousing the patient and if this failed to resolve the desaturation, then oxygen was administered. Thus, the duration of desaturations was largely determined by the actions of the study staff.

Despite these procedural limitations, a plot of the distribution of the duration of individual desaturations (Fig 5) shows that the longest desaturations tended to occur more in the morphine and the oxycodone groups.

SPID48 (ANALGESIC RESPONSE)

Patients were enrolled in the study following their bunionectomy surgery, a process involving manipulation of the portion of the foot bone responsible for the bunion. Once the surgical anaesthetic had sufficiently worn off and pain intensity scores were at least 5 on a 10 point NPRS scale (0= no pain, 10= worst imaginable pain), patients were randomized to study medication. Analgesic effects were based on reductions in pain intensity from the post-surgical baseline, summed over the 48 hr. opioid dosing period during which MoxDuo, morphine or oxycodone were given at 24 mg MED (morphine equivalent dose) once every 6 hours. These summed changes in pain scores is the Sum of the Pain Intensity Differences over 48 hrs. ($SPID_{48}$). The MoxDuo and control group doses employed in the study were selected to achieve comparable analgesic effects in order to enable a valid comparison to be made of potential differences in respiratory function and in the occurrence of vomiting.

Fig 6 – Sum of the Pain Intensity Differences Over 48 Hours



The $SPID_{48}$ scores did in fact show comparable analgesic effects among the treatment groups. No statistically significant differences were found among any of the treatment groups. The MoxDuo group score was 14% better than that of morphine and 4% less than that of oxycodone. These differences are likely due to chance and thus demonstrate that comparable analgesic effects were achieved for the 3 treatment regimens that used morphine equivalent doses of these three opioids.

OVERALL SUMMARY

At equi-analgesic doses, episodes of oxygen desaturation were of shorter duration and less intensity in patients receiving MoxDuo IR compared to those receiving either morphine or oxycodone alone. Using the maximum blood oxygen desaturation values, the MoxDuo IR patients were 4:1 to 5:1 times less likely to suffer a potentially life threatening severe desaturation event compared to those receiving the other opioids. To the best of our knowledge, MoxDuo IR is the first opioid product to demonstrate a lower risk of respiratory depression in a clinical study comparing morphine equivalent (equi-analgesic) doses. Further, this study included a substantial number (40% of the total enrolment) of subjects age 60 years or older, a demographic group that is at enhanced risk of opioid induced respiratory impairment. Thus, the respiratory benefits of MoxDuo were demonstrated in a broad section of the patient population needing opioids for the management of moderate to severe acute pain. This is an important safety advantage; one we expect will differentiate MoxDuo IR in the acute pain market place.