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Phosphagenics achieves biggest milestone yet

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Singapore: Australian drug delivery technology company, Phosphagenics has achieved succes in its multi-dose oxymorphone patch phase I trial in 12 subjects. The phase I trial was conducted at Linear Clinical Research's facility in Perth on 12 healthy volunteers. The trial was designed to characterize the oxymorphone delivery profile from repeated applications of a three-day patch that mimicked a real life pain medication regime.

All 12 subjects demonstrated oxymorphone plasma concentrations well above the threshold therapeutic concentrations produced by the oral long-acting or extended release dosage form (Opana ER) within the first application period of three days. Oxymorphone plasma concentrations increased with repeated patch application, while maintaining the profile desirable for transdermal products. Results demonstrate that the maximum plasma concentration in subjects can be as high as that produced by a single oral dose of the highest strength Opana ER tablet (40 mg).

Overall, the pharmacokinetic profile of oxymorphone resulting from the multiple-dosing regime exceeded expectations and showed plasma concentrations equivalent to those attained by oral dosages used to treat moderate-to-severe chronic pain.

Based on these positive results, Phosphagenics will proceed to a phase II trial, although its emphasis will now shift. Previously it was envisaged that the phase II trial would need to prove that the product was capable of providing analgesia for patients with chronic pain conditions. As the phase I result emphatically answers that question, the focus of the upcoming phase II will now shift to defining the dosage regimes to be used with the product and enhancing its commercial value, rather than demonstrating therapeutic effect.

Dr Harry Rosen, CEO, Phosphagenics, said, "This result represents the biggest milestone in the company's history. It is a world class achievement by Australian researchers. I cannot speak more highly about their efforts and tenacity. While we had previously demonstrated the capability of TPM, for the first time we have delivered a drug that has never before been delivered through the skin at a level comparable to dosing by other means. Additionally, we are tackling a very substantial market opportunity."

The extended release opioid market for the treatment of chronic pain, which is the target market for the oxymorphone patch, is approximately $6 billion per annum. Surveys undertaken on behalf of Phosphagenics have indicated that a successfully

commercialised oxymorphone patch could achieve peak annual sales of between $700 million-to-$1.4 billion.