transdermal drug delivery technology

OBJ LIMITED

PRESS RELEASE

Thursday, 7 December 2006

OBJ REDUCES TIME TO ONSET IN SUCCESSFUL DOUBLE BLIND HUMAN CLINICAL TRIAL

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OBJ Limited (ASX: OBJ) is pleased to announce the successful completion of the second phase of the company's human clinical trial into the enhanced transdermal delivery of the local anaesthetic Ametop, which uses Tetracaine as its active ingredient.

The combined results of this study and the earlier April study show that Dermaportation was able to induce numbness in volunteer subjects within 20 minutes using one fifth of the recommended drug dosage. This represents a significant reduction in both the amount of drug required and the time to onset compared to manufacturers recommended times of 30-45 minutes.

At 20 minutes after drug administration, there were statistically significant differences in the touch sensitivity between active and placebo treatment areas in volunteers. This provides evidence of successful enhanced skin penetration of tetracaine under the influence of Dermaportation.

A single volunteer study was run in parallel, using 15 minute Dermaportation and drug contact time, which produced greater numbness than the control. This suggests that the Dermaportation technology may be effective in even less time than used in the study.

The human trial, which was conducted by Curtin University's School of Pharmacy, involved 14 adult volunteers (7 female, 7 male). Dermaportation was applied using 4 electronic coil "patches" of which 2 were active and two were placebo. Separate investigators were used to assign active and placebo patches to patients, apply the local anaesthetic and to conduct the measurement processes. In this manner, the study was fully blinded.

Two different tests were conducted at 20 minutes post application and at 20 minute intervals thereafter. Touch sensation was tested using an electronic von Frey device while the blunt/sharp sensation was tested using mechanical means.

5 patients were eliminated from the data pool due to allergic reactions to the drug and pre-existing injuries that may alter normal perception levels.

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At the completion of the study, the University concluded that:

- Dermaportation decreased the time to onset of anaesthesia of Ametop, with a statistically significant difference at 20 min post administration (von Frey data). This provides evidence of the in vivo skin penetration enhancement effect of the Dermaportation technology.

Data from Volunteer G007 suggests that it may be possible to obtain Dermaportation enhanced loss of sensation with Ametop with a 15 min administration period, a significantly shorter period than that currently recommended by the manufacturer (30-45 min: Smith & Nephew product literature).

The ability to improve through-the-skin delivery, reduce the concentration of drug necessary to achieve the desired clinical end-points and reduce the time to onset are aspects of particular importance to the pharmaceutical industry generally.

Dermaportation is uniquely suited to drug delivery applications where enhanced performance of existing products can be achieved without the need for reformulation and re-approval. The simplicity of use of Dermaportation, its painless mode of action and its ability to increase the efficacy of both locally acting and systemic drugs, makes it well suited to a broad range of drugs, products and disease targets.

OBJ is also developing new models and applications specifically for the cosmetic industry. Dermaportation's ability to deliver much larger and more complex molecules through the skin allows cosmetic manufacturers to expand the capabilities of their cosmetic products pipelines.

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Background to the Announcement

The OBJ Dermaportation technology has been shown to manage and control the transdermal delivery of a broad range of drugs and therapeutic agents ranging from small difficult molecules such as Caffeine, through to large macro-globular proteins drugs such as vaccines.

OBJ's technology has been independently proven in both in-vitro and in-vivo studies and can manage a broader range of molecular sizes, structures and valencies than other active or passive drug delivery systems.

OBJ has been successful in managing the through-the-skin delivery of drugs used in the inflammation, pain, cancer and cosmetic fields.

OBJ's technology is low cost, and can be incorporated into reusable drug patches, (as illustrated) disposable single use drug patches and in a range of packaging systems for OTC and retail use.

Sustainable Benefits

Low cost and controlled through-the-skin delivery of drugs, hormones, vitamins, vaccines, anti-bodies and anti-aging molecules has long been the desire of the pharmaceutical industry. It would provide economic, safety and efficacy benefits to the pharmacology, medical, veterinary and cosmetic industries. Side effects could be reduced by localised delivery and programmed delivery rates. Needle stick injuries and needle disposable problems could be eliminated while the reduction in the level of skill required for application could significantly reduce total cost of many health programmes. These clear commercial benefits may only be achievable if the skin's natural barrier effect can be overcome.

OBJ is the first company to create a broad spectrum through-the-skin delivery system that is kind to the skin, completely reversible, yet can handle drugs range from the small difficult molecules up to the largest and most complex proteins and anti-bodies. OBJ manages an extensive IP portfolio and prosecutes patent applications throughout the world.

Independence of Results

OBJ contracts its drug and technology testing programs to independent and respected organisations, such as Western Australian Biomedical Research Institute, Western Australian Institute for Medical Research, Curtin University of Technology and Murdoch University. The high level of independence and international accreditation means that the results attributable to OBJ's proprietary technology can be published and presented at major medical and scientific conferences and forums.

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