ASX Announcement

ASX code: MBP

Metabolic's neuropathic pain drug, ACV1 - Clinical trials update

- ***First patients have been treated with ACV1 in the Phase 2A sciatica trial***
- ***A separate trial to test safety of a higher dose level in healthy volunteers has commenced – important information for regulatory authorities and potential licensing partners***
- ***The three clinical trials for ACV1 in progress or final planning are progressing on time***

Melbourne, 29 November 2006:

Phase 2A trial progressing well and first patients now under treatment

Metabolic Pharmaceuticals Limited (Metabolic) announced today that the first group of patients has started treatment with *ACV1* in the Phase 2A trial for neuropathic sciatic pain. This trial is the first part of a Phase 2A programme that involves two human clinical trials targeting specific neuropathies.

Recruitment of patients with sciatica commenced in September 2006 and these patients will be administered 0.4 mg/kg of *ACV1* and placebo by subcutaneous injection once per day. This trial is designed to investigate the safety and tolerability of *ACV1*, and to examine the effects of the drug in patients with neuropathic sciatic pain. Metabolic expects to have the results of this trial available during the first six months of 2007 (H107).

The second Phase 2A trial in this programme will target diabetic neuropathic pain and post-herpetic neuralgia and is anticipated to commence during the January-to-March 2007 quarter (Q107).

Phase 1 extension trial to test safety of a higher dose of ACV1

Metabolic has also commenced a Phase 1 extension trial for *ACV1*. The purpose of this trial is to study the safety, tolerability and pharmacokinetics of a higher dose of *ACV1* than previously tested in the first Phase 1 trial completed in October 2005.

The clean safety and side effect profile shown in the previous Phase 1 study allows Metabolic to enhance the overall *ACV1* data package by expanding knowledge of the "margin of safety" above the anticipated therapeutic dose. This is important information for regulatory authorities and potential licensing partners. The dose being tested in this Phase 1 extension trial is the highest dose possible using the current formulation. This information will enhance understanding of the drug's safety profile, and may allow higher doses in the clinic, should the human trial data suggest that such an approach would be beneficial.

This Phase 1 extension trial is expected to be completed by late December 2006 with results announced during the January-to-March 2007 quarter (Q107). This Phase 1 extension trial does not impact the timeline for the Phase 2A programme for *ACV1* (referred to above).

Details of the previous Phase 1 trial for *ACV1* (completed in Q405)

The main aims of the earlier Phase 1 trial were to assess the safety, tolerability and pharmacokinetics of both single doses and multiple (7) daily doses of *ACV1* administered by subcutaneous injection. In the trial, 45 healthy male volunteers were administered single and multiple (7 day) doses of *ACV1*, by subcutaneous injection. The study showed no evidence of systemic drug-related adverse effects of *ACV1* at any of the dose levels used in either the single or multiple dose components of the study.

- ENDS -

Appendix: Design for the Phase 1 extension trial - to test the safety of a higher dose of *ACV1*

Phase of development	Phase 1
Patient populations	Healthy male volunteers
Patient selection criteria	Males, aged 18 to 65 years, inclusive
Number of patients	Up to 14
Study centre	CMAX - Clinical Studies Unit (A Division of IDT Australia Ltd) Royal Adelaide Hospital, South Australia
Investigators	Professor Guy Ludbrook, MBBS FANZCA PhD Professor and Head of Anaesthesia, Dept Anaesthesia and Intensive Care, University of Adelaide and Royal Adelaide Hospital
Aims	To determine the safety, tolerability and pharmacokinetics of *ACV1* in healthy human volunteers following single and multiple subcutaneous doses
Doses	*ACV1* dose • 0.8 mg/kg via subcutaneous injection once per day (previous Phase 1 trial tested single and multiple doses up to 0.4 mg/kg)
Design	Randomised, double blind, placebo-controlled, single and multiple dose
Duration	1 day followed by 7 days

Background to *ACV1* and neuropathic pain

- *ACV1* was safe and well tolerated at all administered doses in the first human study (Phase 1 trial) for the drug, announced in November 2005.
- *ACV1* has been tested in several well-established animal pain models and shows efficacy in relieving the characteristic pain symptoms of neuropathy, allodynia and hyperalgesia.
- *ACV1* is a 16 amino acid peptide conotoxin derived from an Australian cone snail. The drug works by blocking a subtype of a class of receptors in the peripheral nervous system call neuronal nicotinic acetylcholine receptors (nAChR).
- Neuropathic pain is the most debilitating form of chronic pain, generated from damaged nerves and serving no beneficial function for the affected individual. Besides diabetes, the common causes of neuropathy are viral infection (e.g. shingles), trauma, sciatica, chemotherapy and various other conditions.
- Neuropathic pain affects 10 million people in the US alone. The current market for neuropathic pain drugs is valued at approximately US$2.5 billion a year and is expected to double in five years.

About Metabolic

*Metabolic Pharmaceuticals Limited (**ASX**: MBP, **NASDAQ OTC**: MBLPY) is a Melbourne based, ASX listed biotechnology company with 285 million shares on issue. The Company employs 24 staff and is led by an experienced and proven management team. Metabolic's main focus is to take innovative drugs, with large market potential, through formal preclinical and clinical development. Metabolic's expertise in drug development has resulted in two high value drugs in advanced human clinical development, namely:*

- *AOD9604 - an obesity drug currently in a Phase 2B trial with results expected in March 2007;*
- *AOD9604 - additional use in osteoporosis with a Phase 2 trial expected to commence in 2007; and*
- *ACV1 - a neuropathic pain drug currently in Phase 2A trials.*

These drugs address multi-billion dollar markets which are poorly served by existing treatments. In addition to its lead drugs, Metabolic has an exciting research pipeline with drugs targeting type 2 diabetes (ADD) and nerve regeneration (NRPs). Metabolic is also developing a platform to enable oral delivery of existing injected peptide drugs, a technology which has already shown proof-of-concept. This has high potential for use by other companies developing peptide drugs and could foster multiple out-licensing deals.

Metabolic may license its lead drugs to a global partner following Phase 2 trials and will continue to utilise its clinical development expertise to drive future company growth and profits

For more information, please visit the company's website at www.metabolic.com.au.

Background information on the drug development process

The steps required before a drug candidate is commercialised include:

1. *Discovery or invention, then filing a patent application in Australia and worldwide;*
2. *Pre-clinical testing, laboratory and chemical process development and formulation studies;*
3. *Controlled human clinical trials to establish the safety and efficacy of the drug for its intended use;*
4. *Regulatory approval from the Therapeutic Goods Association (TGA) in Australia, the FDA in the USA and other agencies throughout the world; and*
5. *Marketing and sales.*

The testing and approval process requires substantial time, effort, and financial resources and we cannot be certain that any approvals for any of our products will be granted on a timely basis, if at all.

Human clinical trials are typically conducted in three sequential phases which may overlap:

Phase 1

Initial safety study in healthy human subjects or patients.

Phase 1 trials usually run for a short duration.

Phase 2

Studies in a limited patient population designed to:

- *identify possible adverse effects and safety risks in the patient population (2A);*
- *determine the efficacy of the product for specific targeted diseases (2B); and*
- *determine tolerance and optimal dosage (2B).*

Phase 3

Trials undertaken to further evaluate dosage and clinical efficacy and to further test for safety in an expanded patient population in clinical study sites throughout major target markets (e.g. USA, Europe and Australia).

Contact Information

Roland Scollay
Chief Executive Officer
roland.scollay@metabolic.com.au
T: +61-3-9860-5700

Peter Dawson
Chief Financial Officer
peter.dawson@metabolic.com.au
T: +61-3-9860-5700

Diana Attana
Assistant Company Secretary/IRO
diana.attana@metabolic.com.au
T: +61-3-9860-5700