Tuesday, 09 April 2002

ASX RELEASE

Phenoxodiol stabilises cancer progression with minimal toxicity

(San Francisco, California, USA) – Preliminary US clinical trial results of the novel anti-cancer drug phenoxodiol indicate that it slowed cancer progression in six out of ten patients at doses that were well tolerated.

The interim trial results were presented today at the 93rd annual meeting of the American Association for Cancer Research (AACR), in San Francisco, by researchers from the Cleveland Clinic's Taussig Cancer Centre, in Ohio, one of the leading cancer treatment centres in the US.

Phenoxodiol represents a new direction for anti-cancer therapy. The drug targets the underlying control mechanism in cells that determine whether a cell will survive or die.

This mechanism malfunctions in cancer cells, preventing them from dying or being killed by drugs. Phenoxodiol targets the activities of key members of this control mechanism including sphingosine kinase and the caspase proteins.

Phenoxodiol was discovered by the Australian pharmaceutical company, Novogen Limited, and is being developed by its US subsidiary, Marshall Edwards Inc.

The Chairman of Marshall Edwards Inc., Dr Graham Kelly, said researchers were very encouraged by this early result.

"The data presented today is consistent with what we have seen in other trials with phenoxodiol, which is stabilisation of cancer growth in some patients without serious toxicity," Dr Kelly said.

"We continue to refine the search for the optimum dose, the best method of administration and the cancer targets that will respond best to phenoxodiol.

"That said, today we are exactly where we expected to be," Dr Kelly added.

Patients on the trial have a variety of cancers that have failed to respond to standard anti-cancer drugs. In the Cleveland trial, phenoxodiol is administered by intravenous infusion for six weeks in the first instance.

Treatment can be continued past six weeks if there is no evidence of tumour progression or serious toxicity. Six of ten patients remained on phenoxodiol beyond six weeks following evidence of stabilisation of the cancer.

The trial's co-investigator, Dr Thomas Hutson said phenoxodiol was an interesting new drug.

"It may target certain proteins in cancer cells that could be the key to the cancer process," Dr Hutson said.

Dr Ronald Bukowski, the Director of Experimental Therapeutics in the Cleveland Clinic Taussig Cancer Centre, said that Phase I clinical trials are mainly about evaluating the safety of new drugs and how to use those drugs, rather than about whether or not the drug works.

"Nevertheless, we are encouraged that phenoxodiol appears to have stabilised tumour growth in six out of the ten first patients that were tested on the drug and that the drug was reasonably well tolerated." Dr Bukowski said.

The cancer types represented by the patients on the trial include colon cancer, melanoma, thymic

cancer, prostate cancer, RCC and TCC.

Toxicity included moderate nausea, fatigue and shortness of breath.

Novogen is a pharmaceutical company based in Sydney, Australia, with offices in Stamford, Connecticut.

Novogen is a leader in the field of multi-acting, signal transduction inhibitor drugs with interests in oncology, cardiovascular and inflammatory disease fields.