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MARSHALL EDWARDS, INC. COMMENCES RENAL CANCER HUMAN TRIAL OF PHENOXODIOL IN COMBINATION THERAPY

(Washington DC and Sydney, Australia) Marshall Edwards, Inc. (NASDAQ : MSHL; LSE-AIM : MSH) has commenced a study that will test the ability of its investigational anti-cancer drug, phenoxodiol, to enhance the effect of platinum drugs in patients with solid cancers, particularly late-stage renal carcinoma (cancer of the kidney).

The study is being conducted at St George Hospital, Sydney, Australia. The Principal Investigator is Paul de Souza MD.

The patients in the study will have late-stage cancers that are no longer responding to standard chemotherapies. These chemotherapies include platinum drugs such as cisplatin and carboplatin, that commonly are used as first-line therapies for a wide range of cancers because of their potency. Most patients eventually become resistant to such drugs, so overcoming that resistance has become an urgent medical need.

In the laboratory, phenoxodiol has shown a potent ability in cancer cells to reverse chemo-resistance to drugs such as cisplatin and carboplatin. The basis of this reversal is thought to be the ability of phenoxodiol to remove blocking proteins such as XIAP (X-linked Inhibitor of Apoptosis Protein) which are over-expressed in cancer cells.

In this study, phenoxodiol will be administered in the oral dosage form. Patients will take capsules of phenoxodiol, in one of four dose strata, three times a day, for treatment cycles of 12 weeks. Patients also will receive either cisplatin or carboplatin once weekly at a fixed dose.

One of the main objectives of the study is to determine the appropriate dose level of phenoxodiol for renal cancer. Studies have shown that phenoxodiol is likely to be more effective at lower, rather than higher doses for a wide range of applications.

Dr. Graham Kelly, Executive Chairman of Marshall Edwards, Inc., said, "Phenoxodiol is an exciting prospect for the reversal of chemo-resistance in late-stage cancers where patients have no therapeutic options remaining. This study is one of a number where we are testing that proposition.

“Preliminary studies to date indicate that phenoxodiol may enhance the ability of drugs such as platinum to kill cancer cells, without impacting normal cells. This study hopes to confirm that.

“Another important objective is to confirm the therapeutic benefit of phenoxodiol combinational therapy in patients particularly those with late-stage renal carcinoma (cancer of the kidney). Based on our clinical experience to date, we have good reason to believe that phenoxodiol has considerable potential in this deadly form of cancer,” Kelly added.

Marshall Edwards, Inc., is pursuing a dual strategy of developing phenoxodiol for the treatment of both early-stage cancers and late-stage cancers. The strategy in early-stage cancers of using phenoxodiol as a monotherapy is intended to result in killing of cancer cells before they have had a chance to develop the pro-survival techniques, involving apoptosis blocking proteins, that characterize many late-stage cancers. The strategy being employed for the late-stage cancers is to use phenoxodiol in combination with standard drugs such as paclitaxel and cisplatin.

Phenoxodiol was developed by Novogen Limited (Nasdaq: NVGN; ASX: NRT) and licensed to Marshall Edwards, Inc. It is an investigational anti-cancer drug that has yet to receive marketing approval by regulatory authorities.

Statements included in this press release that are not historical in nature are “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. You should be aware that our actual results could differ materially from those contained in the forward-looking statements, which are based on management’s current expectations and are subject to a number of risks and uncertainties, including, but not limited to, our failure to successfully commercialize our product candidates; costs and delays in the development and/or FDA approval, or the failure to obtain such approval, of our product candidates; uncertainties in clinical trial results; our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products; competitive factors; our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business; our inability to operate our business without infringing the patents and proprietary rights of others; general economic conditions; the failure of any products to gain market acceptance; our inability to obtain any additional required financing; technological changes; government regulation; changes in industry practice; and one-time events. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.