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## **MARSHALL EDWARDS, INC., NAMES SECOND STUDY SITE IN MULTI-NATIONAL OVARIAN CANCER TRIAL OF INVESTIGATIONAL ANTI-CANCER DRUG PHENOXODIOL**

(Washington, DC June 14, 2004). The Royal Women's Hospital in Melbourne, Australia, today became the second site to enrol cancer patients in a study of the ability of phenoxodiol, to restore the sensitivity of ovarian cancer cells to the standard chemotherapies, paclitaxel and cisplatin. The trial is also being conducted at Yale-New Haven Hospital, Connecticut.

Researchers are evaluating phenoxodiol for its ability to enhance the anti-cancer effect of standard chemotherapies, as well as restore sensitivity in cancers that have become refractory to standard chemotherapies. In the laboratory, phenoxodiol has been found to boost dramatically the ability of low doses of chemotherapy to treat ovarian cancer.<sup>1</sup>

This trial follows a successful Phase I/II study conducted at Yale-New Haven Hospital that looked at phenoxodiol as a monotherapy in late-stage ovarian cancer patients. Researchers from Yale reported at the American Association of Cancer Research conference in April 2004, that subsequent to that trial, four of five patients classified as being refractory to paclitaxel showed a substantial response as determined by Rustin criteria on re-challenge with paclitaxel following a course of phenoxodiol therapy.

Patients in this study will have late-stage ovarian cancer that has become refractory to the standard first-line chemotherapies - paclitaxel and cisplatin. A refractory cancer is one that continues to grow despite chemotherapy. Women on the trial will be randomised to one of three treatment arms – (1) paclitaxel only, (2) paclitaxel plus phenoxodiol, and (3) cisplatin plus phenoxodiol. The paclitaxel-only treatment arm has been included to confirm the refractory status of the cancers, which is a requirement for regulatory approval of drug registration. Women in the paclitaxel-only arm will be offered phenoxodiol plus paclitaxel combination treatment once their refractory status is confirmed.

The development of chemo-resistance in cancers has been associated with the over-production within cancer cells of the anti-apoptotic protein, XIAP<sup>2</sup>. Phenoxodiol has

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<sup>1</sup> Kamsteeg, M., et al., *Nature Oncogene*, 2003 May 1;22(17):2611-20.

<sup>2</sup> Li, J., Feng, Q., Kim, J. M., Schneiderman, D., Liston, P., Li, M., Vanderhyden, B., Faught, W., Fung, M. F., Senterman, M., Korneluk, R. G., and Tsang, B. K. Human ovarian cancer and cisplatin resistance: possible role of inhibitor of apoptosis proteins. *Endocrinology*, **142**: 370-380, 2001.

been found in the laboratory to restore chemo-sensitivity by removal of XIAP, an effect that is restricted to cancer cells.

Michael Quinn, M.D., who is leading the study at the Royal Women's Hospital, said, "This is an opportunity that we hope will provide a benefit for women who have become unresponsive to chemotherapy. Currently we can offer nothing in the way of therapy for these patients, but the promising clinical response that the Yale University Medical School doctors obtained with phenoxodiol in refractory patients gives us cause to hope that that will change."

Phenoxodiol is an investigational drug and, as such, is not marketed in the United States.

Phenoxodiol is developed by pharmaceutical company Marshall Edwards, Inc. (LSE AIM: MSH - Nasdaq: MSHL), which manages its international research and development programs using the expertise and clinical research capabilities of universities and hospitals in the U.S., Australia and Europe.

Marshall Edwards, Inc., has licensed rights to bring phenoxodiol to market globally from its parent company, Novogen Limited. (ASX: Novogen - Nasdaq: NVGN). Novogen is developing a range of therapeutics across the fields of oncology, cardiovascular disease and inflammatory diseases based on its phenolic drug technology platform.

More information on phenoxodiol and on the Novogen group of companies can be found at [www.marshalledwardsinc.com](http://www.marshalledwardsinc.com) and [www.novogen.com](http://www.novogen.com).

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.