

## ASX & MEDIA RELEASE 11 APRIL, 2012

# MARSHALL EDWARDS RECEIVES FDA APPROVAL OF INVESTIGATIONAL NEW DRUG APPLICATION FOR CLINICAL TESTING OF ONCOLOGY DRUG CANDIDATE ME-344

Novogen Limited's subsidiary, Marshall Edwards, Inc., (NASDAQ: MSHL), has made the following announcement:

San Diego – 10 April, 2012 – Marshall Edwards, Inc., an oncology company focused on the clinical development of novel therapeutics targeting cancer metabolism, announced today that it has received approval from the US Food and Drug Administration (FDA) for its Investigational New Drug (IND) application for ME-344, the company's lead mitochondrial inhibitor. The company is now in the process of initiating a Phase I clinical trial of intravenous ME-344 in patients with solid refractory tumours.

"With this important milestone, we have now successfully advanced our two most promising oncology drug candidates into the clinic," said Daniel P Gold PhD, President and Chief Executive Officer of Marshall Edwards. "As we near the completion of our Phase I clinical trial of ME-143 and prepare for its next phase of development, we are excited to initiate our first human study of ME-344. We believe ME-344 is a novel compound that has the potential to significantly improve treatment outcomes for patients with cancer, but first it is important to confirm its safety and tolerability in patients while establishing an optimal dose for future trials."

The Phase I clinical trial of ME-344 is being conducted in collaboration with the Sarah Cannon Research Institute. The open-label, dose-escalation trial will evaluate the safety and tolerability of intravenous ME-344 in patients with refractory solid tumours. In addition, the trial is designed to characterise its pharmacokinetic profile and describe any preliminary clinical anti-tumour activity observed. Patients will be administered intravenous infusions of ME-344 once weekly for three weeks and, after safety assessment, may continue weekly dosing if a clinical benefit is determined. The trial is expected to enrol up to 24 patients at three sites. Additional information regarding the trial, including enrolment criteria and site information, is available on the US National Institutes of Health (NIH) clinical trials database at <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a>.

### About ME-344

ME-344 is the company's lead mitochondrial inhibitor and an active metabolite of NV-128, a first-generation compound. In April, 2011, Ayesha Alvero MD, Department of Obstetrics, Gynecology and Reproductive Sciences at Yale University School of Medicine, presented data at the American Association for Cancer Research Annual Meeting from a pre-clinical study of NV-128 demonstrating its ability to induce mitochondrial instability, ultimately leading to cell death in otherwise chemotherapy-resistant ovarian cancer stem cells. These results were later published in the August, 2011 issue of *Molecular Cancer Therapeutics*. In additional pre-clinical studies, ME-344 has demonstrated far superior anti-tumour activity against a broad range of human cancer cell lines compared to NV-128, including breast, colorectal and ovarian. Marshall Edwards owns exclusive worldwide rights to all of its drug candidates, including ME-344.

#### **About Marshall Edwards**

Marshall Edwards, Inc. (Nasdaq: MSHL) is a San Diego-based oncology company focused on the clinical development of novel therapeutics targeting cancer metabolism. The company's lead drug candidates, ME-143 and ME-344, have been shown in laboratory studies to interact with specific enzyme targets resulting in inhibition of tumour cell metabolism, a function critical for cancer cell survival. Marshall Edwards initiated a Phase I clinical trial of intravenous ME-143 in patients with solid refractory tumours in September, 2011 and plans to present safety and pharmacokinetic data from the trial at the American Society of Clinical Oncology Annual Meeting in June, 2012. The company received approval of its Investigational New Drug application for ME-344 in April, 2012 and is in the process of initiating a Phase I clinical trial of intravenous ME-344 in patients with solid refractory tumours. For more information, please visit <a href="https://www.marshalledwardsinc.com">www.marshalledwardsinc.com</a>.

### **About Novogen Limited**

Novogen Limited (ASX: NRT NASDAQ:NVGND) is an Australian biotechnology company based in Sydney, Australia. Novogen conducts research and development on oncology therapeutics through its subsidiary, Marshall Edwards, Inc., and is developing glucan technology through its subsidiary, Glycotex, Inc. More information on the Novogen group of companies can be found at <a href="https://www.novogen.com">www.novogen.com</a>.

ISSUED FOR : NOVOGEN LIMITED

LISTINGS : ASX (CODE NRT), NASDAQ (CODE NVGN).

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