

# ASX & MEDIA RELEASE 30 MAY, 2012

## MARSHALL EDWARDS ANNOUNCES FIRST COHORT OF PATIENTS DOSED IN PHASE I CLINICAL TRIAL OF ONCOLOGY DRUG CANDIDATE ME-344

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

San Diego – 29 May, 2012 –Marshall Edwards, Inc., an oncology company focused on the clinical development of novel therapeutics targeting cancer metabolism, announced today that the first cohort of patients has been dosed in a Phase I clinical trial of ME-344, the Company's lead mitochondrial inhibitor drug candidate, in patients with refractory solid tumours. The dose escalation trial is expected to enrol up to 24 patients in up to five cohorts with final safety and pharmacokinetic data expected in the first half of 2013.

"We are very pleased to see the excitement surrounding our initial clinical trial of ME-344, with the first cohort of patients now well underway just a month after our Investigational New Drug application was approved by the FDA," said Robert D Mass, MD, Chief Medical Officer of Marshall Edwards. "ME-344 is a novel compound that showed compelling anti-tumour activity in preclinical studies. Now we look forward to gathering valuable clinical data in the months ahead, all of which will help to optimise the design of our Phase II efficacy studies."

The Phase I clinical trial is evaluating the safety and tolerability of intravenous ME-344 in escalating dose cohorts of 1.2 mg/kg, 2.5 mg/kg, 5 mg/kg, 10 mg/kg and 20 mg/kg. In addition, the trial is designed to characterise the pharmacokinetic profile of ME-344 and describe any preliminary clinical anti-tumour activity observed. Patients in the trial are 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 open-label trial is being conducted in collaboration with the Sarah Cannon Research Institute at three sites: Florida Cancer Specialists in Sarasota; University of Oklahoma in Oklahoma City; and Tennessee Oncology in Nashville. Additional information regarding the trial, including enrolment criteria, is available on the US National Institutes of Health (NIH) clinical trials database at www.clinicaltrials.gov.

#### About ME-344

ME-344 is Marshall Edwards' lead mitochondrial inhibitor and an active metabolite of NV-128, the Company's first-generation compound. In April, 2011, Ayesha Alvero, M.D., 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 preclinical 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 initiated a Phase I clinical trial of intravenous ME-344 in patients with solid refractory tumours shortly thereafter. For more information, please visit www.marshalledwardsinc.com.

### **About Novogen Limited**

**INFORMATION:** 

Novogen Limited (ASX: NRT NASDAQ:NVGN) 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).

FOR FURTHER : PETE DE SPAIN, SR DIRECTOR IR AND CORPORATE

COMMUNICATIONS, MARSHALL EDWARDS, INC.

TEL +1 858-792-3729

http://www.marshalledwardsinc.com

ISSUED BY : WESTBROOK COMMUNICATIONS CONTACT : IAN WESTBROOK TEL (02) 9231 0922