ASX ANNOUNCEMENT

International post-approval clinical trial commences ahead of schedule

HIGHLIGHTS

• First patient enrolled, six months ahead of schedule
• Leading US cancer centre, Vanderbilt-Ingram Cancer Center, first site named in international trial
• Inclusion of major cancer centres in trial, expected to drive further market adoption of ImpediMed’s L-Dex® device

Brisbane, Australia – ImpediMed Limited (ASX: IPD) (“the Company”) is pleased to announce that the international, post-approval clinical trial has commenced six months ahead of schedule with the enrolment of its first patient.

The purpose of the trial is to objectively establish the clinical utility of ImpediMed’s L-Dex device, used for the early detection of lymphoedema. The commencement of the trial marks a new phase in ImpediMed’s commercial rollout of L-Dex, with interim data from the trial to be used as the company seeks coverage from private health insurers in the US. The inclusion of major cancer centres in the trial will also drive market adoption as the CPT® Category 1 Code (government pay code) comes into effect on 1 January 2015.

The randomised control trial will enrol 1,100 patients and is led by Principal Investigator Professor Sheila H. Ridner, PhD, FAAN, of the Vanderbilt University School of Nursing. Patient enrolment is expected to be completed in approximately two years and will be conducted in at least five sites in the US and Australia.

“Data from this trial will provide unique insights into patient outcomes following early detection of lymphoedema and we believe will lead to improved approaches in preventing progression of this often incapacitating, long-neglected condition,” said Richard Carreon, President and CEO of ImpediMed.

“The post approval trial is a defining event for the company and adds to growing body of evidence highlighting the benefits of early detection of lymphoedema using L-Dex. The inclusion of prestigious sites such as Vanderbilt University will help to accelerate market adoption and the data collected will be important in our dialogue with private payors in the US,” he added.

“There is an opportunity to make a difference for these patients. I am fully committed to conducting rigorous research that will meet the aims of the study”, said Professor Sheila H. Ridner, PhD, FAAN, of the Vanderbilt University School of Nursing and Principal Investigator in the trial.

Details of the clinical trial can be found at the US National Institutes of Health website: http://clinicaltrials.gov/ct2/show/NCT02167659?term=impedimed&rank=6
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About ImpediMed
ImpediMed Limited is the world leader in the development and distribution of medical devices employing Bioimpedance Spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of fluid status. ImpediMed’s primary product range consists of a number of medical devices that aid surgeons, oncologists, therapists and radiation oncologists in the clinical assessment of patients for the potential onset of secondary lymphoedema. Pre-operative clinical assessment in cancer survivors, before the onset of symptoms, may prevent the condition from becoming a lifelong management issue and thus improve the quality of life of the cancer survivor. ImpediMed has the first medical device with an FDA clearance in the United States to aid health care professionals, clinically assess secondary unilateral lymphoedema of the arm and leg in women and the leg in men.

For more information, visit: www.impedimed.com.au