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## **ASX / MEDIA RELEASE**

### **ImpediMed Lodges FDA Application to clinically assess Lymphoedema in the Arm**

ImpediMed Limited (ASX: IPD) today announced the achievement of a major milestone, lodging an application with the US Food and Drug Administration (FDA) to market the company's new L-Dex U400 device.

ImpediMed CEO Greg Brown said the announcement of the FDA application lodgement for the L-Dex U400 FDA marked yet another key step in achieving the milestones forecast in the company's prospectus.

In April 2007, ImpediMed received its first lymphoedema related FDA clearance for the Imp XCA, a medical device aimed at the clinical assessment of secondary lymphoedema in the arm. Long term, the XCA device is targeted for homecare use, primarily for breast cancer survivors.

ImpediMed is best known for the development and sales of products targeting early clinical assessment of lymphoedema resulting from breast cancer. Listed on 24 October 2007, ImpediMed raised \$18 million in its initial public offering with a key focus on expanding its market approach in the area of monitoring lymphoedema in cancer survivors, with a key part of that expansion being the completion of a suite of products to offer surgeons and oncologists.

Mr Brown said the L-Dex U400 will be ImpediMed's first platform targeting healthcare professionals such as surgeons, oncologists and physical therapists.

"This improved design uses the lymphoedema index (L-Dex) measurement system pioneered by the Imp XCA device, but unlike its predecessor, which employs low frequency impedance, the L-Dex U400 is an advanced bioimpedance spectroscope incorporating dynamic results viewing, tracking and data transfer functionalities that are optimised for the busy clinical environment. It is targeted at Health Care Providers and medical research markets globally."

Mr Brown said support is starting to build for a new preemptive approach to assessing and treating breast cancer survivors for Lymphoedema and ImpediMed will offer the first FDA cleared device to assist in this earlier clinical assessment of patients..

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“Bioimpedance spectroscopy and single low frequency impedance devices can make an important contribution to the early assessment of lymphoedema, enabling the clinician to commence intervention at the earliest opportunity.”

One thought leader getting behind the new clinical management paradigm is Dr. Steven Schonholz, M.D., FACS, Medical Director of the Breast Care Center at Mercy Medical Center, Springfield Massachusetts.

“Impedimed’s technology allows me to get a baseline on all of my surgical patients and follow them through their treatment course. I evaluate them postoperatively, prior to radiation, upon completion of radiation, prior to chemotherapy and monthly throughout their chemotherapy and on routine follow appointments every six months initially and then changing to yearly,” Dr Schonholz said.

“By identifying those patients up to ten months prior to clinical findings, I am able to treat the lymphoedema and prevent the chronic lymphoedema of the past. I consider the XCA/U400 a new standard of care that should be practiced not only at breast centers, but all practices that deal with breast cancer.”

“When I originally discuss breast cancer, I review all the surgical options for the breast and then discuss sentinel node and axillary dissection. Following this discussion, I bring up the XCA and how I will obtain a baseline on them preoperatively and that I will follow them postoperatively. I tell patients that the device can pick up increased fluid in the arm up to ten months earlier before becoming clinically evident.”

“All my patients are amazed and are eager to have the study. I tell them we are the only one in the area doing this for our patients and they always ask why? While it makes complete sense to me it also makes complete sense to all of my patients. They do not understand that if the technology is out there, why is it not being used everywhere,” concluded Dr Schonholz.

ImpediMed CEO Greg Brown said the company would move to launch the L-Dex U400 to surgeons, oncologists and physical therapists as soon as FDA clearance is obtained.

“The L-Dex U400 is the device we feel will maximise clinical utility to this group of specialists and will assist in driving the adoption of both the technology and the early detection early intervention treatment paradigm.”

**For more information contact:**

Mel Bridges  
Greg Brown  
John Lamont

ImpediMed Limited – Chairman  
ImpediMed Limited – CEO  
Phillips Group – Media Relations

Office: +61-7-3423-1777  
Office: +61-7-3423-1777  
Mobile: +61-408-737-450

- **About ImpediMed Limited:**

ImpediMed Limited develops and globally markets medical device systems for use in non-invasive screening and monitoring of human disorders and diseases.

ImpediMed has bases in the US and Australia, and is primarily focused on addressing the major health issue of Lymphoedema in cancer survivors.

ImpediMed's primary product range consists of a number of medical devices that enable the early clinical assessment and monitoring of secondary lymphoedema in cancer survivors before the onset of symptoms that are detectable using the most commonly used clinical technique.

ImpediMed has the only medical device with an FDA clearance in the United States for the clinical assessment by Health Care Providers of secondary lymphoedema in the arm.

L-Dex, XCA and U400 are trademarks of ImpediMed Limited

[www.impedimed.com](http://www.impedimed.com)

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