ASX: IPD

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ASX RELEASE:

L-DEX OUTCOMES DATA FROM BREAST CANCER LYMPHOEDEMA PREVENTION PROGRAM

Brisbane, Australia. – **ImpediMed Limited** (ASX: IPD) ("the **Company** or **ImpediMed**") would like to make shareholders aware of clinical data that was presented over the weekend in New York City at the MASCC/ISOO - 2012 International Symposium on Supportive Care in Cancer. The clinical outcomes data was directly linked to the use of L-Dex® U400 technology (BIS) in a routine setting for helping lymphoedema prevention in breast cancer patients at Magee-Womens Hospital of UPMC.

The use of L-Dex U400 in the lymphoedema prevention program was as a clinical aid for helping physicians identify subclinical lymphoedema in patients with either axillary lymph node dissection (ALND) or sentinel lymph node biopsy (SLNB) with radiation therapy. The L-Dex U400 measurements were obtained pre-operatively for baseline and then post- operatively every 3 to 6 months for the first year.

Four hundred and ninety-seven (497) patients are recorded in the UPMC Breast Cancer Lymphoedema prevention program database and to date none have progressed to clinical lymphoedema. A total of one hundred and twenty-eight (128) patients had completed L-Dex assessment prior to their surgery, to determine their baseline L-Dex unit, and all patients had between 3 to 9 months of follow up readings. Of these one hundred and twenty-eight (128) patients, sixteen (16) were detected as having subclinical lymphoedema (incidence of 13%). All 16 patients received early intervention. The use of an over the counter compression sleeve, physical therapy, daily exercise, and reducing the use of the affected arm defined early intervention.

There were another one hundred and twenty-nine (129) patients who underwent breast cancer surgery prior to the start of the program who were measured by L-Dex as part of their 3 month follow-up visit (Wellness Clinic). These readings were taken as baseline for patients if no clinical breast cancer related lymphoedema (BCRL) and no symptoms existed.

Combining both groups, which demonstrates patients after surgery with L-Dex readings (128 + 129 patients), of the two hundred and fifty-seven (257) patients, a total of thirty-six (36) patients were diagnosed with a subclinical lymphoedema (overall incidence of 14%). In the presented results, all subclinical patients received early intervention for lymphoedema and no patients had progressed beyond a sublicnical state.

The conclusion drawn from the data collected from the Magee Womens Hospital was that early detection and timely intervention demonstrated the greatest promise of reducing the incidence of late-stage lymphoedema. UPMC also anticipated, with an extended period of follow-up, a delay or elimination of more advanced breast cancer related lymphoedema (BCRL) in the future. This is important for women who already face and struggle with breast cancer and its morbidities.

“The ability to detect the earliest signs of lymphoedema is critical to our program,” said Dr. Soran. “While lymphoedema can’t be cured, interventional strategies such as exercise, physical therapy and compression treatments can successfully help control its progression.” Dr. Soran went on to say, “In addition to the physical complications lymphoedema causes, it is expensive to manage in its latter stages. Approximately $3 billion a year is spent on managing lymphoedema, and that number doesn’t include the cost of a patient’s disabilities, loss of wages or pain management. We hope our program can continue to improve the lives of our patients while reducing the cost burden of lymphoedema."

Greg Brown, CEO of ImpediMed, commented on the clinical data, “This is the first presentation of clinical outcomes, based on the use of L-Dex in a prospective care model. It resembles the findings of the pivotal interventional study that was published in the Cancer Journal in 2008. The data helps demonstrate that L-Dex can 1) through extracellular fluid measurement identify patients with subclinical lymphoedema, 2) help prevent progression through early intervention, and 3) demonstrate compliance of patients to a prevention program with the use of L-Dex in routine clinical use.” He went on to say, “This outcomes data will strengthen the existing clinical data on technical and diagnostic performance, critical for health insurers to cover for prospective testing and treatment.”

One of the highest incidences of lymphoedema in the U.S. occurs following breast cancer surgery, particularly among those who undergo radiation therapy following lymph node surgery. Among this group, up to 25 to 30 percent of patients develop some degree of upper extremity lymphoedema. While there are differing degrees of severity, lymphoedema can severely affect a person’s quality of life, with complications ranging from fatigue, impairment of daily activities, recurrent bacterial infections and embarrassment due to the size and shape of the affected limb.

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About L-Dex

L-Dex® is a trademark of ImpediMed Limited.
The L-Dex® scale is a tool to aid in the clinical assessment of unilateral lymphoedema of the arm and leg in women and the leg in men by a medical provider. The L-Dex® scale is not intended to diagnose or predict lymphoedema of an extremity.

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