ASX: IPD

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Australian Securities Exchange Announcement

IMPEDIMED ACHIEVES MILESTONE WITH FDA CLEARANCE FOR AIDING IN THE CLINICAL ASSESSMENT OF UNILATERAL LIMBS

ImpediMed Limited (ASX: IPD) (the Company) today announced that it has achieved another major milestone with the U.S. FDA (the Agency) clearance of the Company's L-Dex® U400 device to aid in the clinical assessment of unilateral lymphoedema of the arm in women, and legs for both men and women. Additionally, the Agency has allowed the indication to be expanded to include patients who will have, or who have had lymph nodes from the axillary and pelvic regions removed, damaged or irradiated. This broadens the claim beyond just cancer and no longer links it to any one specific cancer. The Company sees this as an additional major expansion of the available market.

This clearance also recognizes the prospective model of care as it allows for baseline and subsequent follow up of patients at risk and more aligns the indication with U.S. clinical standards and guidelines. The Company's value proposition is built off advancing prospective care for patients at risk of unilateral lymphoedema in both the arms and legs, and this expanded claim now covers this promotion.

Mr. Brown said "the FDA clearance paves the way for ImpediMed to directly launch the device into the U.S. market for limbs. ImpediMed will market the L-Dex U400 device directly with its U.S. sales force and will initially target general surgeons who specialize in the breast and other cancers (e.g. melanoma), radiation oncologists and therapists", he said. He further added, "that while this will now open up the market to a broader base of medical providers, for both male and female patients, that the Company would not lose its current primary focus on breast cancer".

"The FDA clearance of the L-Dex U400 device puts us in a strong position to build awareness in all of ImpediMed's target markets for lymphoedema and for driving adoption of the L-Dex technology" said Mr Brown. "The L-Dex U400 is considered the first product designed specifically to meet the needs of the routine clinical environment for surgeons (oncology and vascular), radiation oncologists and therapists".

"The increasing mantra from global experts in managing patients at risk of lymphoedema is the recognition of the critical coordination and collaboration needed between the surgeon, oncologist and the therapist. Paramount to this is the requirement for a standardised metric that can aid in the early detection of the disorder. Through prospective care, patients with the early signs of lymphoedema, can now be referred by their surgeon/oncologist to an appropriately trained therapist for the earliest possible initiation of treatment. This will help prevent progression of the lymphoedema

to irreversible stages. All other patients, who remain at life time risk of lymphoedema, can be better educated and monitored for their long term well being by their primary care provider." said Mr Brown.

Lymphoedema can be an extremely debilitating medical condition, and if not detected early, may progress to an irreversible lifelong impairment and disfigurement. Treatment may involve exercise, compression bandaging, pumps and manual lymph drainage. Recent findings from the U.S. National Institute of Health have demonstrated that periodic assessment and early intervention can effectively return patients to a pre-surgical state and help protect their quality of life.

Mr. Brown said "The ImpediMed L-Dex U400 device has the potential to play a critical role in the prospective assessment, education and optimal coordination of the clinical management of lymphoedema in patients at risk of unilateral lymphoedema of the limbs." He went on to say that, "the next new indication the Company was looking to expand with the FDA was the bilateral lymphoedema claim for legs in both males and females".

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The L-Dex scale is a tool to assist in the clinical assessment of lymphoedema by a medical provider. The L-Dex scale is not intended to diagnose or predict lymphoedema of an extremity.

About ImpediMed

ImpediMed Ltd. 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 breast 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 lymphoedema of the arm in female breast cancer patients.

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