



17 April 2018

ASX ANNOUNCEMENT

US FDA 510(k) Clearance for Bilateral Lymphoedema Assessment with SOZO®

Brisbane, Australia and Carlsbad, Calif. - ImpediMed Limited (ASX: IPD) a global provider of medical technology to non-invasively measure, monitor and manage fluid status and body composition, is pleased to announce the issuance by the US FDA of a 510(k) clearance to market SOZO® as an aid in the clinical assessment of bilateral lymphoedema in adult patient's arms or legs. This new clearance reflects the SOZO® system's ability to assess patients at risk of bilateral lymphoedema, where a patient is at risk in either both arms or both legs.

This clearance greatly expands the available market for our technology. Of the approximately 1 million new cancer cases per year in the US alone which put survivors at risk of limb lymphoedema, only 25% of them are breast cancers. The other 75% are pelvic-area cancers or melanoma, which most often put survivors at risk of bilateral lymphoedema. SOZO® with unilateral and bilateral L-Dex® allows clinicians to monitor all of these survivors with confidence, effectively quadrupling the total available market. The previous L-Dex® U400 device was not capable of assessing bilateral lymphoedema.

"We are excited for this new clearance and what it means for the patients we serve" said Richard Carreon, Managing Director and CEO of ImpediMed. "Now SOZO® is able to aid in the clinical assessment of lymphoedema in the upper and lower extremities for both women and men who are at-risk of developing this debilitating chronic disease due to their cancer care. This is a significant advancement in our goal to play a greater role in the broader cancer market."

"This, our third 510(k) clearance in under 12 months for the SOZO® platform, follows our recent clearance for monitoring fluid levels in heart failure patients, achieving yet another important regulatory milestone in our journey of providing a new and improved model of care, across the patient care continuum."

SOZO® utilizes ImpediMed's bioimpedance spectroscopy (BIS) technology to perform a full scan of 256 frequencies to provide both detailed and accurate information on the fluid status of patients. Studies have shown detectable differences in extracellular fluid using ImpediMed's BIS devices as low as 36 ml in limbs and 100 ml in whole-body measurements.

Richard Carreon
Managing Director & CEO

Media Contact:

Kyahn Williamson, WE Buchan

T: +61 3 9866 4722

E: kwilliamson@buchanwe.com.au

About ImpediMed

Founded and headquartered in Brisbane, Australia with US and European operations, ImpediMed is the world leader in the design and manufacture of medical devices employing bioimpedance spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of tissue composition and fluid status.

ImpediMed produces a family of FDA cleared and CE Marked medical devices, including SOZO® for multiple indications including heart failure and lymphoedema, sold in select markets globally.

For more information, visit www.impedimed.com.