

impedi**med**

ImpediMed Receives FDA 510(k) Clearance of SOZO® for Expanded Indication

Becomes first device cleared for Protein Calorie Malnutrition Assessment

Carlsbad, CA, and Brisbane, Australia – Dec. 11, 2019 - ImpediMed Limited (ASX:IPD), a medical software technology company that non-invasively measures, monitors and manages fluid status and tissue composition using bioimpedance spectroscopy (BIS), recently announced the issuance of a further 510(k) clearance for SOZO® by the U.S. Food and Drug Administration (FDA). SOZO is the first device to gain FDA clearance for use as an aid in the assessment of Protein Calorie Malnutrition.

The expanded clearance enables ImpediMed to market SOZO for assessing patients at risk of Protein Calorie Malnutrition (PCM) and to track clinically relevant body composition parameters over time in both healthy and unhealthy patient populations. SOZO will aid clinicians who are using Subjective Global Assessment (SGA) tools to assess patients at risk of PCM.

Malnutrition is a largely under-recognized health problem. Greater than one-third of patients in the U.S. are malnourished prior to being admitted to the hospital. Further, one-third of patients not malnourished at the time of admission, become malnourished during their stay at the hospital.¹

According to the U.S. National Cancer Institute, at the time of cancer diagnosis, 80% of patients with gastrointestinal cancer and 60% of patients with lung cancer have already experienced significant involuntary weight loss. Additionally, malnutrition is common among outpatients with heart failure (HF) and is strongly related to increased mortality. In a recent study to determine the prevalence and prognostic consequences of malnutrition in HF patients, they found 57% of the HF patients were at least mildly malnourished as measured by at least one nutritional index.²

Nationally, the annual direct medical cost of disease-associated malnutrition is over \$15.5 billion.¹

SGA tools such as the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) guidelines define changes in physical attributes as assessment criteria for PCM in patients. SOZO provides quantitative values for fluid accumulation, muscle and fat mass to provide robust, objective data, critical to nutritional evaluations, and can be used by clinicians to support their assessment and diagnosis of PCM.

A recent study published in the [*Journal of the American Medical Association*](#) titled “Association of Nutritional Support With Clinical Outcomes Among Medical Inpatients Who Are Malnourished or at Nutritional Risk” demonstrates the clinical benefit of nutritional support in malnourished patients.

“Many chronic diseases, including cancer, COPD, CHF and liver disease, are associated with PCM,” according to Scott C. Howell, D.O., MPH & TM, Chief Medical Officer at Vitality Healthplan. “The consequences can be significant, including increased mortality, prolonged hospital stays and poor

impedimed

wound healing. A proactive, screening-based approach for nutritional support, employing SOZO, could lead to significantly improved clinical outcomes for patients."

1. Goates S, Du K, Braunschweig CA, Arensberg MB (2016) Economic Burden of Disease-Associated Malnutrition at the State Level. PLoS ONE 11(9): e0161833. doi:10.1371/journal.pone.0161833
2. Sze S., Pellicori P., Kazmi S., et al. (2018) Prevalence and prognostic significance of malnutrition using 3 scoring systems among outpatients with heart failure: a comparison with body mass index. J Am Coll Cardiol HF 6:476–486.

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 lymphedema, sold in select markets globally.

For more information, visit www.impedimed.com.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to expand sales and market acceptance in the US and Australia including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. ImpediMed does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. ImpediMed may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

Media Contact:

Ned Berkowitz
Russo Partners
(646) 942-5629
ned.berkowitz@russopartnersllc.com