28 November 2019

ASX ANNOUNCEMENT

US FDA 510(k) Clearance for Protein Calorie Malnutrition Assessment

Brisbane, Australia – 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), today announced the issuance by the US FDA of a further 510(k) clearance for SOZO®.

The new 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 healthy and unhealthy patient populations. Specifically, the claims around PCM are to aid clinicians who are using Subjective Global Assessment (SGA) tools to assess patients at risk of PCM.

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. Weight, muscle mass, fat mass and oedema are tracked and reported by SOZO and can be used by clinicians to support their assessment and diagnosis of PCM.

“We are pleased that this submission to the FDA included real-world evidence. This clearance will expand our clinical utility and footprint in the oncology space,” said Richard Carreon, Managing Director and CEO of ImpediMed.

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About ImpediMed
Founded and headquartered in Brisbane, Australia with US and European operations, ImpediMed is a medical software technology company that non-invasively measures, monitors and manages fluid status and tissue composition using bioimpedance spectroscopy (BIS).

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.

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 commercialise 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.