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#### **ASX ANNOUNCEMENT**

# 2-Year Trajectory Analysis Shows Significant Benefit of BIS

**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 publication of a trajectory analysis of the PREVENT study that further demonstrates the clear clinical benefit of BIS. The results of the study, published online in *Cancer Medicine*, establish the use of BIS as the primary detection tool for subclinical lymphoedema.

The analysis showed that BIS detection of lymphoedema was statistically significantly associated with patient symptoms through 2 years whereas tape measure detection of lymphoedema was not. The paper concluded "Statistically significant convergence of symptom cluster scores with L-Dex® unit change support BIS as beneficial in early identification of subclinical lymphoedema."

The data was presented as a trajectory analysis showing the course of patients monitored by BIS or tape measure and correlated to symptoms. Trajectory analyses are used to analyse longitudinal data, enabling the understanding of how risk factors for diseases develop over time. This is especially important for early detection and disease prevention. The published analysis included the same patient cohort of 508 patients that were in the previously published PREVENT 1-year interim analysis with additional triggers as expected in months 13 through 24.

"The findings from the two-year trajectory analysis clearly establish the clinical benefit of BIS in early identification of subclinical lymphoedema and provides additional evidence to support the American Physical Therapy Association's recommendation that BIS be used for measurement of subclinical lymphoedema," said Dr. Sheila Ridner, PhD, RN, FAAN, the principal investigator of PREVENT and the Martha Rivers Ingram Professor of Nursing at Vanderbilt University School of Nursing. "The PREVENT trial remains on track to complete this year with the final outcomes data available early in the new year. Maintaining the integrity of the PREVENT trial is paramount and prohibits us from releasing further outcomes data prior to the measurement of the primary endpoint comparing BIS to tape measure. In the meantime, studies such as trajectory and others, are providing invaluable information for our better understanding and treatment of lymphoedema."

"This data analysis strengthens the case to make surveillance programs for early detection using L-Dex mandatory." said Rick Carreon, Managing Director and CEO of ImpediMed. "We believe that the trajectory paper in conjunction with the Meta-Analysis and other soon to be published papers, will provide the basis of a strong submission for the inclusion of BIS, as an objective measure for the early detection of lymphoedema, in the NCCN Guidelines<sup>®</sup>."

A link to the manuscript can be found here: <a href="https://onlinelibrary.wiley.com/doi/full/10.1002/cam4.3188">https://onlinelibrary.wiley.com/doi/full/10.1002/cam4.3188</a>

Approved for release by the Managing Director and CEO, Mr Richard Carreon.

#### **Contact Details**

# **Investor relations Contact:**

Mike Bassett, ImpediMed

T: +61 407 431 432

E: mbassett@impedimed.com

# **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 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, protein calorie malnutrition and lymphoedema, sold in select markets globally.

For more information, visit www.impedimed.com.

# **About the PREVENT Trial**

The PREVENT trial is an international, multi-institutional, randomised controlled trial designed to follow over 1,100 patients for three years at 10 medical centers across the US and Australia. Patients enrolled in the study included breast cancer survivors whose treatment puts them at risk for developing secondary, chronic lymphoedema in one of their arms. These patients were randomised to follow up monitoring for lymphoedema development using either L-Dex or tape measure-based volume measurements.

#### **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.