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ASX ANNOUNCEMENT

PREVENT Trial Successful, Statistically Significant Results

ImpediMed Limited (ASX.IPD) is pleased to announce the PREVENT Trial successfully met its primary endpoint. This study, which provides level I evidence, demonstrated that intervention in patients with early detection of cancer-related lymphoedema using ImpediMed's L-Dex® technology resulted in a lower rate of progression to chronic disease than patients with early detection from volume measurements using a tape measure, a result that is statistically significant. These findings, available as a preprint on medRxiv.org, were based on 1,200 patients followed for up to 3 years across 13 hospitals in the US and Australia.

The results are as follows:

- The trial met its primary endpoint.
- In patients with early detection using L-Dex, intervention resulted in a 7.9% rate of chronic lymphoedema compared to a 19.2% rate of chronic lymphoedema in patients with early detection using tape measure (p=0.016).
- This represents an absolute reduction of 11.3% and relative reduction of 59%.
- 92% of patients with early detection of cancer-related lymphoedema using L-Dex and intervention did not progress to chronic lymphoedema.

The paper concludes the following:

- These statistically significant results demonstrate that bioimpedance spectroscopy (BIS) screening should be a standard approach for prospective breast cancer-related lymphoedema (BCRL) surveillance.
- BIS is more specific for lymphoedema detection than tape measure (TM), as it had fewer triggers and longer times to intervention trigger.
- While the BIS protocol can be easily replicated in clinical settings, the rigor of the TM protocol for this study exceeded what is practical in most clinics. Thus, BIS may offer even more benefit across clinical settings than what was demonstrated in this study.
- BIS, as compared to TM, provides a more precise identification of patients likely to benefit from an early compression intervention.

The PREVENT trial is a pivotal study, the largest randomised controlled trial to assess lymphoedema prevention. The study enrolled 1,200 patients across 10 trial sites in the US and Australia, involving 13 hospitals, including Vanderbilt University, Mayo Clinic and MD Anderson. The trial was conducted over six and a half years and patients were followed for up to three years, with the primary aim to determine if early intervention in patients with subclinical detection of extracellular fluid accumulation via bioimpedance spectroscopy results in a lower rate of lymphoedema progression versus the rate when tape measure is used for subclinical detection.

The Company believes these results, combined with previously published data, will give clinicians the information they need to begin early intervention on their patients at a stage when it's possible to keep the lymphoedema from advancing. There is strong support for the prospective surveillance model for early intervention with the National Comprehensive Cancer Network® (NCCN®) clinical practice

guidelines supporting the need for pre-treatment and on-going measurement of patients at risk for lymphoedema and that better patient outcomes are reached with early detection. When the peer-reviewed paper is published, these results will provide all clinicians addressing lymphoedema in breast cancer patients clear scientific data regarding the optimal measurement and sound evidence to switch from using tape measurements.

The paper has been reviewed and, with the feedback to date, the Company remains confident it will be published in a peer-reviewed journal in the coming months. The preprint allows the results to be shared without compromising the peer-review process. The Company can now more effectively plan its future and more adequately prepare for the next steps including preparation of submissions to the National Comprehensive Cancer Network clinical practice guidelines (NCCN Guidelines®) and private medical insurance companies in the United States.

“I would like to thank the participants and the investigators for their hard work and dedication over the past several years. These results are significant, not just for ImpediMed, but for cancer patients and survivors at risk of lymphoedema,” said Richard Carreon, Managing Director and CEO of ImpediMed.

“This study is consistent with the previous studies showing regular monitoring with L-Dex and simple intervention substantially reduce the risk of developing cancer-related lymphoedema. What differentiates this study is, for the first time, we have a level I randomised controlled trial of sufficient size and duration to result in a statistically significant difference between the outcomes using L-Dex and Tape Measure. When the peer-reviewed paper is published, this will expand the opportunity for providers to be reimbursed for L-Dex testing, which we believe will result in a significantly wider and quicker adoption of the SOZO® technology,” he continued.

A link to the preprint manuscript can be found here:
https://www.medrxiv.org/content/10.1101/2021.10.12.21264773v1

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

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About ImpediMed
Founded and headquartered in Brisbane, Australia with US and European operations, ImpediMed is a medical technology company that uses bioimpedance spectroscopy (BIS) technology to generate powerful data to maximise patient health.

ImpediMed produces a family of FDA cleared and CE Marked medical devices, including SOZO® for multiple indications including heart failure, lymphoedema, and protein calorie malnutrition 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.