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ASX ANNOUNCEMENT

PREVENT Trial Peer-Reviewed and Published

ImpediMed Limited (ASX.IPD) is pleased to announce the PREVENT Trial results have been peer-reviewed and published in *Lymphatic Research and Biology*, a journal dedicated to research on lymphatic biology and pathology from the world's leading biomedical investigators. The study 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.

The publication's conclusion, which was not amended from the preprint released on 19 October 2021, stated "[L-Dex] screening should be a standard approach for prospective breast cancer-related lymphoedema surveillance."

"This timely knowledge gives 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," said Principal Investigator Sheila H. Ridner, PhD, RN, FAAN, research professor at Vanderbilt University School of Nursing. "These findings provide all clinicians addressing lymphoedema in breast cancer patients with clear scientific data regarding the optimal measurement and sound evidence to switch from using tape measurements."

"That is a victory for patients, particularly the 1,200 breast-cancer patients who volunteered for this study. I thank them and all the collaborators at 13 hospitals across the US and Australia for their dedicated work over several years," she continued.

"The results of this study provide clarity for patients and clinicians regarding breast cancer-related lymphoedema (BCRL) screening and early intervention," added Dr. Chirag Shah, Director of Breast Radiation Oncology and Director of Clinical Research in the Department of Radiation Oncology at Cleveland Clinic and co-investigator of the PREVENT Trial.

He continued, "The primary outcome demonstrated the benefit of prospective monitoring with L-Dex coupled with early intervention in reducing rates of chronic lymphoedema, which is important clinically due to the impact of chronic BCRL on patients' quality of life. One of the most significant components of the results was the risk-adjusted analysis. When looking at key risk factors for BCRL, including body weight, stage of cancer, type of cancer surgery, lymph node dissection, chemotherapy, and radiation, the benefit of using L-Dex monitoring was consistent and showed the utility of L-Dex across a large group of breast cancer patients."

About the PREVENT Trial

The PREVENT Trial has successfully demonstrated, with statistical significance (*p-value* 0.016), that early detection and intervention using ImpediMed's L-Dex technology results in a significantly lower rate of progression of breast cancer-related lymphoedema (BCRL) to chronic disease when compared to initiating the intervention from volume measurements using a tape measure.

The results were 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.
- A risk-adjusted analysis showed a significantly consistent benefit of L-Dex monitoring in a large group of patients with key risk factors for BCRL including body weight, stage of cancer, type of cancer surgery, lymph node dissection, chemotherapy, and radiation (odds ratios: 0.23-0.39).

The paper concluded 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 and 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.

“I want to thank the patients and investigators involved in the PREVENT trial for their hard work and dedication,” said Richard Carreon, Managing Director and CEO of ImpediMed.

“Today we reached a significant milestone that will change the trajectory of the company. Randomised trials of this size are the highest level of scientific evidence and PREVENT will help us expand access to L-Dex testing for millions of patients worldwide. PREVENT shows to the world that our bioimpedance spectroscopy (BIS) technology can detect medically meaningful fluid shifts in the body. In the case of L-Dex, we measure fluid shifts as small as 36 mL. As we look to other diseases like heart failure and renal failure, where we track whole body fluid changes, we expect to achieve similar transformations in patient care,” he added.

A link to the manuscript can be found here:
https://www.liebertpub.com/doi/10.1089/lrb.2021.0084

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

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.

Click here for more information on PREVENT

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.