



ImpediMed Announces PREVENT Interim Results – “Practice-Changing”

Following >1,100 breast cancer survivors, PREVENT is the largest, multi-site randomized controlled trial (RCT) ever performed to study lymphedema prevention

Carlsbad, Calif. and Brisbane, Australia – May 6, 2019 – ImpediMed Limited (ASX: IPD), a global provider of medical technology to non-invasively measure, monitor and manage tissue composition and fluid status using bioimpedance spectroscopy (BIS), today announces the publication of the peer-reviewed manuscript of the PREVENT interim analysis.

Sheila H. Ridner, Ph.D., RN, FAAN, principal investigator of PREVENT and the Martha Rivers Ingram Professor of Nursing at Vanderbilt University School of Nursing, delivered the interim results at a podium presentation during the 20th Annual Scientific Meeting of American Society of Breast Surgeons in Dallas, Friday, May 3, 2019.

These interim results are important and support the use of subclinical detection with BIS and early intervention for patients with breast cancer at risk for lymphedema. While the results did not reach statistical significance at this time, they were demonstrated to be clinically meaningful and thus practice-changing.

The paper concluded: “The results of this interim analysis demonstrate that patients undergoing surveillance with BIS had reduced but non-statistically significant reductions in the rates of progression requiring CDP compared with TM. These results are currently supportive of the need for subclinical detection and early intervention for patients with BCRL, with a 10% absolute reduction and 67% relative reduction in the rates of CDP. Further data with a longer follow-up than in this study is expected in the years to come and will strengthen these early, positive, practice-changing results.”

The manuscript was published in the *Annals of Surgical Oncology*, the most cited surgical oncology journal. It is also one of the most cited surgical journals in the world, with nearly 14,000 citations in 2016 to articles published within the last five years.

A copy of the manuscript is available [here](#).

Dr. Ridner states, “These early findings mean that the majority of women could potentially avoid this debilitating condition if BIS screening were the norm. My hope is that someday every breast cancer patient at risk will have access to this valuable tool.”

Academy award winning actress and LE&RN spokesperson, Kathy Bates presented the keynote address at the meeting, speaking on her personal journey with lymphedema. She advocated for pre-operative measures and post-surgical prospective monitoring with L-Dex. Bates says, “Patients can now take advantage of technology like L-Dex by ImpediMed...to measure lymph flow prior to surgery and after to determine if there are any changes indicating that a patient is at risk to develop lymphedema because the earlier one starts the better the outcome.”

Richard Carreon, managing director and CEO, ImpediMed, says, “We now have the evidence from a randomized controlled trial that supports the findings from multiple real-world studies that the use of BIS in a prospective surveillance model does improve patient outcomes. We are confident that we will reach the study endpoint as the current data represents less than half the patients and with only 1/3 of the follow up duration completed.”

About ImpediMed

Founded and headquartered in Brisbane, Australia, with U.S. 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. Visit www.impedimed.com.

About BIS

Bioimpedance spectroscopy (BIS) differs fundamentally from other bioimpedance approaches. ImpediMed’s BIS devices measure impedance at 256 different frequencies

over a full spectrum from 3 kHz to 1000 kHz and do not depend upon population-specific prediction equations to generate fluid volumes or tissue masses. ImpediMed's BIS technology does not assume that extracellular fluid (ECF) and intracellular fluid (ICF) are uniformly distributed. Therefore, this technique provides a more direct and individualized measure of ECF, ICF, and total body water (TBW) compartments of the body compared with other approaches. This has significant advantages, particularly in-patient populations with altered fluid homeostasis.

Abbreviations:

BCRL – breast cancer related lymphedema
BIS – bioimpedance spectroscopy
CDP – complex decongestive physiotherapy
LE&RN – the Lymphatic Education and Research Network
TM – tape measure

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