

6 May 2019

### **ASX ANNOUNCEMENT**

# PREVENT Interim Results – "Practice-Changing"

**Brisbane, Australia and Carlsbad, Calif.** – <u>ImpediMed Limited</u> (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 announced the publication of the peer-reviewed manuscript of the PREVENT interim analysis.

Sheila H. Ridner, PhD, RN, FAAN, the 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 20<sup>th</sup> Annual Scientific Meeting of American Society of Breast Surgeons, in Dallas, Texas on Friday 3<sup>rd</sup> May 2019.

These interim results are important and support the use of subclinical detection with bioimpedance spectroscopy (BIS) and early intervention for patients with breast cancer at risk for lymphoedema. 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 that "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 and 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 at:

### https://link.springer.com/article/10.1245%2Fs10434-019-07344-5

Dr. Ridner stated, "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, Ms Kathy Bates presented the key note address at the meeting, speaking on her personal journey with lymphoedema. She advocated for pre-operative measures and post-surgical prospective monitoring with L-Dex. Ms Bates said "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 lymphoedema because the earlier one starts the better the outcome."

Richard Carreon, Managing Director and CEO of ImpediMed, said, "We now have the evidence from a randomised controlled trial that supports the findings from multiple real-world studies that the use of BIS in a prospective surveillance model significantly improves 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."

# Richard Carreon Managing Director & CEO

#### **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 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 lymphoedema, sold in select markets globally.

For more information, visit www.impedimed.com.

## **Abbreviations:**

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