# impedimed

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## ASX ANNOUNCEMENT

# **PREVENT Trial Enrolment Reaches 1,100 Patients**

**Brisbane, Australia and Carlsbad, Calif.**- ImpediMed Limited (ASX: IPD) a global provider of medical technology to non-invasively measure, monitor and manage tissue composition and fluid status, today announced that it achieved a major milestone with the enrolment of the targeted 1,100 patients in the PREVENT Trial.

The PREVENT Trial is the largest international multicentre randomised controlled trial (RCT) undertaken in the prevention of breast cancer-related lymphoedema. The trial commenced in 2014 and is led by Sheila H. Ridner, PhD, FAAN, the Martha Rivers Ingram Professor of Nursing at Vanderbilt University School of Nursing. The study has been designed to determine if the use of bioimpedance spectroscopy (BIS) to identify the earliest signs of swelling, enabling treatment at a time when it is most effective, prevents the progression of breast-related lymphoedema.

"We are extremely grateful to the patients and their families for their contribution to this very important study," said Ridner. "We are pleased with how the PREVENT Trial is going and we believe it will provide new scientific insight into the course of lymphoedema for breast cancer survivors. The first manuscript generated from the study has been submitted for editorial review and is expected to be published upon completion of the review. Interim analysis will be submitted shortly."

Patients in the trial are randomised to regular monitoring either with BIS or with tape measure for up to three years post-surgery. If they meet the criteria for treatment, they are prescribed compression garments for 28 days. If the swelling does not resolve or increases, patients are referred on for further treatment and the early intervention has been deemed to be unsuccessful.

Despite advances in surgical techniques, lymphoedema remains a significant challenge for patients following breast cancer treatment. Incident rates are highest in patients who have had any one or more of the following: extensive surgery, six or more lymph nodes removed from their axilla, radiation therapy and taxane-based chemotherapy. Lymphoedema begins as a swelling not apparent to the eye. If left untreated it progresses to a chronic condition manifested by visibly swollen arm and tissue changes. Patients experience symptoms of pain, numbness, infections, loss of function and decreased quality of life.

Bioimpedance spectroscopy detects changes in extracellular fluid of the limb. Use of BIS technology to identify when changes occur enables treatment at the earliest time point. The earlier the condition is identified the less intense the treatment needs to be.

Richard Carreon Managing Director & CEO

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### About ImpediMed

Founded and headquartered in Brisbane, Australia with U.S. offices in Carlsbad, Calif. and Bloomington, Minn., and a European office in Thessaloniki, Greece, 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 was the first company to receive FDA clearance in the U.S. to aid healthcare professionals to clinically assess unilateral lymphoedema of the arm and leg in women and the leg in men, for its L-Dex<sup>®</sup> device. In addition, ImpediMed produces a family of FDA cleared and CE Marked medical devices, including SOZO<sup>™</sup>, sold in select markets globally.

For more information, visit www.impedimed.com.