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ASX ANNOUNCEMENT

Landmark Radiation Manuscript Supports L-Dex® Use

Brisbane, Australia – ImpediMed Limited (ASX.IPD), a medical software technology company that non-invasively measures, monitors and manages fluid status and tissue composition using bioimpedance spectroscopy (BIS), today announced the publication of a sub-analysis of the PREVENT study that demonstrates the benefit of BIS L-Dex® in detecting subclinical breast cancer-related lymphoedema (sBCRL) compared to tape measure. Further, the study, published in the prestigious *International Journal of Radiation Oncology, Biology and Physics*, contributes new insight into the role of regional nodal irradiation on the incidence of breast cancer-related lymphoedema.

The analysis concluded that the "lower triggering rates with BIS and its better discrimination of the risk of sBCRL by receipt and type of regional node irradiation (RNI) as compared to tape measure (TM) support its use for post treatment surveillance to detect sBCRL and initiate early intervention. The risk of sBCRL increased with more extensive axillary treatment."

The study was performed by world-renowned radiation oncologists and investigators from the PREVENT study. Data from the PREVENT trial over a 2-year period was analysed to determine the incidence of sBCRL stratified by the extent of treatment by surgery and/or level of radiation.

Previous studies have demonstrated an increase in the risk of breast cancer related lymphoedema (BCRL) as the extent of surgical treatment and RNI increases. The purpose of this study was to compare the risk of sBCRL using L-Dex BIS or tape measure by the extent of regional nodal irradiation and extent of surgical treatment. The patient risk was analysed by comparing the outcomes across the following groups:

- Screening type
  - BIS L-Dex or
  - Tape measure
- Extent of regional node irradiation
  - Extensive (if it included radiation to the supraclavicular fossa (SCF) or the upper parts of the axilla (Level III) or
  - Limited if it only included the lower axilla (Level I-II)
- Extent of surgical treatment
  - Extensive was defined as axillary lymph node dissection (ALND)
  - Limited was defined as sentinel node biopsy (SNB)

Study Results

1. 109 of 498 patients (21.9%) triggered (BIS 13.5% vs TM 25.6%, p<0.001).
2. In patients not receiving RNI, BIS triggered 12.9% of patients undergoing SNB and 25% undergoing ALND (p=0.18).
3. Extensive RNI significantly increased triggering with BIS versus no RNI after SNB (33.3% vs 12.9%, p=0.03) but not ALND.
4. Triggering by TM was over 25% for most subgroups and was inferior, demonstrating TM's inability to discriminate the risk of sBCRL by utilisation of RNI or axillary surgery.

The analysis had three important findings:

1. When BIS was used as the monitoring tool, there was clear differentiation of sBCRL incidence by the extent of treatment to the axilla. Patients who had either extensive axillary surgery and/or extensive RNI had a higher incidence of sBCRL. However, when tape measure was used as the monitoring tool there was no differentiation based on extent of surgery and with or without RNI.
2. The study found that the use of extensive RNI significantly increased the risk of sBCRL irrespective of the extent of surgery to the axilla, and that monitoring with BIS was better able than tape measure to identify this increase compared to patients not receiving RNI.
3. BIS was demonstrated to be a more objective measure of extracellular fluid and is less influenced by fat and/or muscle changes which effect volume measures, with the 24-month incidence of sBCRL detecting a statistically significant difference (p=0.0001), 16% for BIS compared to double with TM (30%).

When commenting on the results Professor John Boyages AM, radiation oncologist at ICON Cancer Centre and lead author of the study concluded, "The results support the use of BIS over tape measure as a preferred tool in the post-treatment surveillance to detect subclinical breast cancer-related lymphoedema and initiate early intervention. Because the risk of sBCRL increased with more extensive axillary treatment, patients having any axillary surgery together with extensive RNI require close surveillance for BCRL." He added, "In this era of personalised medicine and improved outcomes with chemotherapy and targeted therapies, consideration should be given to avoiding the SCF/Level III of the axilla for selected patients when appropriate."

"This is a significant study that further adds to the growing body of clinical evidence. The contrasting ability of BIS L-Dex to align with the known risk factors for breast cancer-related lymphoedema when compared to tape measure is emphasised in this study and it demonstrates the effectiveness of ImpediMed's BIS L-Dex technology in identifying subclinical breast cancer-related lymphoedema," stated Rick Carreon, Managing Director and CEO of ImpediMed. "This paper, together with the soon to be published Meta-Analysis, will form the basis of what we believe will be a strong submission to the NCCN in the coming months," he added.

A link to the publication can be found here:
https://www.redjournal.org/article/S0360-3016(20)34440-0/fulltext

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 software technology company that non-invasively measures, monitors and manages fluid status and tissue composition using bioimpedance spectroscopy (BIS).

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.

About the PREVENT Trial
The PREVENT trial is an international, multi-institutional, randomised controlled trial designed to follow over 1,100 patients for three years at 10 medical centers across the US and Australia. Patients enrolled in the study included breast cancer survivors whose treatment puts them at risk for developing secondary, chronic lymphoedema in one of their arms. These patients were randomised to follow up monitoring for lymphoedema development using either L-Dex or tape measure-based volume measurements.

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.

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