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ASX ANNOUNCEMENT

Meta-Analysis: BIS L-Dex Statistically Significant Reduction in Lymphoedema

Key Highlights

- **Overall, BIS L-Dex® achieved an 81% relative reduction in the rate of chronic lymphoedema when compared with tape measure with a p-value of <0.001.**
- **In every high-risk subgroup evaluated, BIS L-Dex achieved significant reductions in the incidence of chronic lymphoedema with p-values of <0.001.**
- **The results are both statistically (p<0.001) and clinically significant demonstrating patients monitored with BIS L-Dex were significantly less likely to develop chronic BCRL.**
- **Tape measure underperformed the background group, highlighting that tape measure does not identify subclinical lymphoedema.**
- **The meta-analysis was performed on 50 eligible studies and included >67,000 women with breast cancer with follow up ranging from 8 months to 3.9 years.**
- **The meta-analysis and the recently published Boyages, et al. paper will together form a strong submission to the NCCN.**

Brisbane, Australia –
ImpediMed Limited (ASX.IPD), a medical technology company that uses bioimpedance spectroscopy (BIS) technology to generate powerful data to maximise patient health, today announced the publication of a meta-analysis, demonstrating the effectiveness of ImpediMed's L-Dex® measure utilising bioimpedance spectroscopy technology (BIS L-Dex) in reducing the relative subsequent incidence rates of chronic breast cancer-related lymphoedema (BCRL) by 81% when compared to circumference monitoring (tape measure).

The difference is both statistically (p<0.001) and clinically significant demonstrating patients monitored with BIS L-Dex were significantly less likely to develop chronic BCRL. Importantly, patients monitored with BIS L-Dex had a lower incidence rate even in high-risk populations (studies with >40% mastectomy and >50% axillary lymph node dissection (ALND) rates). These findings support the wider use of prospective BIS L-Dex screening as compared to circumference measurements or no surveillance in order to benefit patients at risk of BCRL.

The meta-analysis, titled *The Impact of Monitoring Techniques on Progression to Chronic Breast Cancer Related Lymphedema: A Meta-Analysis Comparing Bioimpedance Spectroscopy versus Circumferential Measurements*, was performed on 50 eligible studies, including 27 prospective surveillance studies and 9 randomised controlled trials. Including the studies used for background lymphoedema rates, the total number of women with breast cancer included in the analysis was >67,000 with follow up ranging from 8 months to 3.9 years.

The purpose of the meta-analysis was to evaluate BCRL incidence rates among patients monitored by BIS L-Dex compared to patients monitored using circumference (tape measure) measures or patients having no standardised monitoring (background). A meta-analysis provides a high level of evidence when rating strength of research, as it integrates all relevant evidence and provides a more reliable answer than a single study.

The overall analysis found the following:

1. **Overall, BIS-monitored studies had an 81% relative reduction in the rate of chronic BCRL when compared with circumference-monitored studies (3.1% with BIS vs. 17.0% with circumference) with a p-value of <0.001.**
2. Irrespective of the trial follow-up duration (<2 years or >2 years), there is a statistically significant reduction in the incidence of BCRL when comparing BIS L-Dex with circumference measure or background, both with p-values <0.001.
3. Irrespective of study type (prospective, randomised controlled trial or retrospective studies), there is a statistically significant reduction in the incidence of BCRL when comparing BIS with circumference measure or background, all with p-values <0.001.
4. The background group had a lower rate of BCRL compared to the circumference measure group.

The large number of patients in the meta-analysis allowed for analysis of at-risk subgroups, demonstrating a statistically significant reduction in BCRL when comparing BIS surveillance to circumference surveillance:

1. In the studies where >50% of the patients underwent ALND, the BIS-monitored studies had a 56% relative reduction in progression of BCRL when compared to the circumference-monitored studies with a p-value of <0.001.
2. In the studies where >50% of the patients underwent sentinel lymph node biopsy (SLNB), the BIS-monitored studies had a 77% relative reduction in BCRL when compared to the circumference-monitored studies with a p-value of <0.001.
3. In the studies where >40% of the patients underwent mastectomy, the BIS-monitored studies had a 79% relative reduction in BCRL when compared to the circumference-monitored studies with a p-value of <0.001.
4. In all three of the above-mentioned subgroups, the incidence rate of BCRL was higher in the circumference-monitored studies when compared to background group.

The paper made the following conclusions:

1. Evidence suggests that monitoring with BIS allowing for early intervention, significantly reduces the relative risk of chronic BCRL, with a 69% and 81% reduction compared to background and circumference measurements, respectively.
2. Circumference monitoring did not appear to provide a benefit with respect to chronic BCRL incidence.
3. Based on these results, BIS should be considered for BCRL screening in order to detect subclinical BCRL and reduce rates of chronic BCRL, particularly in high-risk patients.

Chirag Shah, MD, Radiation Oncologist and Director of Clinical Research and Director of Breast Radiation Oncology in the Department of Radiation Oncology at the Cleveland Clinic and primary author of the study, noted, “The results of this analysis confirm the utility of BIS as part of BCRL screening in reducing rates of long-term BCRL as compared to circumference measures (i.e., tape measure) or no monitoring. What is striking is the reduction with BIS surveillance, which showed an 81% relative decrease in BCRL with BIS as compared to circumference measures. The fact that the analysis is both statistically and clinically significant really stresses the need for widespread prospective BCRL surveillance with BIS.”

“These findings are significant and are an important step forward in our goal to eliminate breast cancer-related lymphoedema,” said Richard Carreon, Managing Director and CEO of ImpediMed. “The meta-analysis demonstrates the effectiveness of L-Dex in reducing BCRL when compared to tape measure and will form the basis of what we believe will be a strong submission to the NCCN in coming months. This Level 1 evidence is a key step in making L-Dex the standard of care for all patients at risk of developing breast cancer-related lymphoedema,” he continued.

A link to the publication can be found here:
https://link.springer.com/article/10.1007/s10549-020-05988-6

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 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.

For more information, visit www.impedimed.com.

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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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