



4 June 2020

ASX ANNOUNCEMENT

Clarification: Statistical Significance & Reported P-Value

The ASX has requested clarification of yesterday's announcement, 2-Year Trajectory Analysis Shows Significant Benefit of BIS, to include the corresponding P-Values.

Statistically significant findings in the manuscript, titled *L-Dex, arm volume, and symptom trajectories 24 month after breast cancer surgery* ("trajectory manuscript"), were defined as the Bonferroni-corrected P-Value <.05.

The statistically significant findings and corresponding P-Values are as follows:

1. the association between the L-Dex® and the symptom cluster score of LSIDS was P=0.031 and
2. the association between the L-Dex and the symptom cluster score of FACTB was P=0.044

As per yesterday's announcement, a link to the full report can be found below. The following are excerpts from the page 1 Abstract of the trajectory manuscript:

Results: Three subclinical trajectories were identified for each biomarker (decreasing, stable, increasing) and symptom cluster scores (stable, slight increase/decrease, increasing). Subclinical lymphedema was identified throughout the 24-month period by each biomarker. An L-Dex increase at 15 months in the BIS group was noted. The self-report sets demonstrated contingency coefficients of 0.20 (LSIDS-A soft tissue, **P = .031**) and 0.19 (FACTB+4, **P = .044**) with the L-Dex unit change trajectories.

Conclusions: These data support the need for long-term (24 months) prospective surveillance with frequent assessments (every 3 months) at least 15 months after surgery. **Statistically significant convergence of symptom cluster scores with L-Dex unit change supports BIS as beneficial in the early identification of subclinical lymphedema.**

The trajectory manuscript highlights the clear clinical benefits of BIS over tape measure, and moreover brings into question the efficacy of tape measure as an effective means of detecting subclinical lymphoedema. This data analysis strengthens the case to make surveillance programs for early detection using L-Dex mandatory. The trajectory manuscript, in conjunction with the Meta-Analysis and other soon to be published papers, will provide the basis of a strong submission for the inclusion of BIS, as an objective measure for the early detection of lymphoedema, in the NCCN Guidelines®.

A link to the manuscript can be found here:

<https://onlinelibrary.wiley.com/doi/full/10.1002/cam4.3188>

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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, protein calorie malnutrition and lymphoedema, 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.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. ImpediMed does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. ImpediMed may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.