



30 January 2023

ASX ANNOUNCEMENT

New Version of NCCN Guidelines® for Breast Cancer

ImpediMed Limited (ASX:IPD), today announced that the National Comprehensive Cancer Network® (NCCN) released a new version of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer on 27 January 2023. The section on lymphoedema remains unchanged.

Salient Points

NCCN Breast Cancer Panel Update

- The new version of the Breast Cancer guidelines, Version 1.2023, incorporating changes from the August 2022 annual meeting, were released.
- The section on lymphoedema remains unchanged, but, importantly, the references linking the Breast Cancer guidelines directly to the Survivorship guidelines remain.
- The Survivorship Panel findings are still pending (see below for details).
- The transparency documents related to the Breast Cancer guidelines, that list what submissions were considered and the rationale behind the decisions, are yet to be released (see below for details).

NCCN Survivorship Panel Submission

- An independent submission was also made to the NCCN Survivorship Panel.
- The NCCN Survivorship Panel met in October 2022 to review all submissions and vote on updates to the guidelines.
- A new version of the NCCN Guidelines for Survivorship is still pending.
- Based on the timing of recent releases, the Survivorship guidelines would likely be published before ImpediMed's Q3 2023 results are released in April 2023.
- The Survivorship Panel includes a lymphoedema subpanel, so there will be a clear understanding of lymphoedema and the unique solution bioimpedance spectroscopy (BIS) offers cancer survivors.

Breast Cancer Panel [Transparency Process](#)

- To ensure transparency in the NCCN Guidelines update process, meeting evidence is published following every update to the guidelines.
- The meeting evidence for the 1.2023 version of the NCCN Guidelines for Breast Cancer has not yet been published.
- The transparency documents typically include changes made to the NCCN recommendations, a short summary of the Panel discussion and the rationale for decisions.
- The transparency documents related to the Breast Cancer guidelines, that list what submissions were considered and the rationale behind the decisions, are yet to be released.
- The NCCN typically releases the transparency documents within one week after guideline updates.

Reiterating Dual Path Approach to Reimbursement

- Reimbursement remains the Company's highest priority.
- The Company continues to pursue a dual pathway strategy of Private Payor Reimbursement via direct submissions to payors and establishing standard of care through submissions to NCCN.
- The Company continues to make solid progress with Private Payor Reimbursement / Coverage to obtain coverage policies with health plans. A further update on the progress of the reimbursement program will be provided in the 4C quarterly results being held on 30 January 2023.
- The second pathway is inclusion in the NCCN Guidelines for Breast Cancer or Survivorship.
- Guideline inclusion, including NCCN, is an accelerator, but not the only path to broader reimbursement coverage.
- Either Private Payor Reimbursement / Coverage or NCCN Guidelines inclusion would establish BIS as standard of care and accelerate adoption of ImpediMed's L-Dex[®] technology.

Approved for release by Managing Director and CEO, Mr Richard Valencia.

Contact Details

Investor Relations Contact:

Mike Bassett, ImpediMed

T: +61 407 431 432

E: mbassett@impedimed.com

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 SOZO Digital Health Platform

SOZO, the world's most advanced, non-invasive bioimpedance spectroscopy (BIS) device, delivers a precise snapshot of fluid status and tissue composition in less than 30 seconds. Using ImpediMed's BIS technology, SOZO measures 256 unique data points over a wide spectrum of frequencies from 3 kHz to 1000 kHz. Results are available immediately online for easy data access and sharing across an entire healthcare system. The FDA-cleared, CE-marked and ARTG-listed digital health platform aids in the early detection of secondary lymphoedema, provides fluid status for patients living with heart or renal failure, and can be used to monitor and maintain overall health – all on a single device.

For more information, visit: <https://www.impedimed.com/products/sozo/>.

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.