27 March 2023

ASX ANNOUNCEMENT

NCCN Guidelines Updated to Recommend Regular Screening for Lymphoedema including with Bioimpedance Spectroscopy

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 Survivorship on 24 March 2023, which now, for the first time, include bioimpedance spectroscopy (BIS).

Key Points

- The NCCN Guidelines® specifically name bioimpedance spectroscopy as an objective measurement tool to identify early signs of lymphoedema.
- The NCCN Guidelines now recommend regular screening for all cancer survivors at risk of lymphoedema.
- The recommendations made by the NCCN Survivorship Panel were Category 2A, which means that there was uniform NCCN consensus for this new recommendation.
- The inclusion of BIS in the NCCN Guidelines will help establish BIS as standard of care and accelerate adoption by Private Payors and Providers.

The NCCN Guidelines are the globally recognised standard for clinical direction and policy in cancer care, with the goal of improving patient care and outcomes. The NCCN Guidelines for Survivorship recognise an individual as a cancer survivor from diagnosis through the balance of their life. Importantly, these NCCN Guidelines apply not only to breast cancer survivors, but all cancer survivors. The updated NCCN Guidelines recommend that cancer survivors at risk of lymphoedema undergo lymphoedema screening at regular intervals to identify early signs of lymphoedema via symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy.

ImpediMed has the only FDA-cleared BIS technology for the assessment of lymphoedema. The Company's SOZO® Digital Health Platform is broadly accepted and recognised for effective and accurate screening of lymphoedema.

New Recommendations

The NCCN Guidelines for Survivorship includes two references to BIS technology in the sections called SLYMPH-2 and SLYMPH-3. SLYMPH-2 lists the principles of lymphoedema, which now recommend that survivors at risk for lymphoedema should be regularly screened for lymphoedema by symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy. SLYMPH-3 outlines an algorithm for assessing and treating survivors at risk of lymphoedema. Two important changes from the prior version are the transition from performing clinical assessment only on survivors reporting lymphoedema symptoms to assessing all survivors at risk of lymphoedema and the addition of a new step to screen patients using a clinical examination and recommends BIS, if available.

The NCCN Guidelines for Survivorship Version 1.2023 can be accessed by registering for an account here:
https://www.nccn.org/login?ReturnURL=https://www.nccn.org/professionals/physician_gls/pdf/survivorship.pdf

Uniform NCCN Consensus
The recommendations made by the NCCN Survivorship Panel were Category 2A, which means that there was uniform NCCN consensus for this new recommendation. The panel meeting minutes show that 28 of 28 panelists in attendance at the meeting voted yes for the changes to SLYMPH-2. For SLYMPH-3, 27 of the 28 panelists in attendance voted yes and 1 abstained. This means that there were not any no votes for either change.

Most large private insurance companies use the Category 2A recommendation from the NCCN Guidelines as the basis for coverage policy determinations.

A full description can be found at the following link:
https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines

Comments from the Managing Director & CEO
Richard Valencia, Managing Director and CEO of ImpediMed stated: "The recommendation in the NCCN Guidelines for the use of bioimpedance spectroscopy technology is a major validating moment for the Company. The authors of the NCCN Guidelines are world leaders in global cancer care driven by sound clinical evidence and patients' best interests. Their recommendations are highly influential for clinicians, patients, policymakers, and insurance companies."

"We will take the information in these updated NCCN Guidelines and immediately integrate it into our reimbursement strategy to expand coverage of SOZO testing for lymphoedema. Our near-term focus remains leveraging our strong clinical evidence, market position, and now these guidelines to drive growth and adoption of our solution for breast cancer-related lymphoedema. Longer-term, these guidelines also support an opportunity to expand into other cancer types, broaden our footprint in oncology, and benefit even more patients," he continued.

The Company plans to hold a conference call later in the week to further update shareholders, with more details to follow.

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

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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 a pivotal study, the largest randomised controlled trial to assess lymphoedema prevention. This international, multi-institutional randomised controlled trial provided level I evidence demonstrating that intervention in patients with early detection of cancer-related lymphoedema using ImpediMed's L-Dex® technology resulted in a lower rate of progression to chronic disease than patients with early detection from volume measurements using a tape measure. The statistically significant results demonstrated that bioimpedance spectroscopy (BIS) screening should be a standard approach for prospective breast cancer-related lymphoedema (BCRL) surveillance. The trial followed over 1,200 patients for three years across 13 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.

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.