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ASX ANNOUNCEMENT

SOZO Pro Achieves Clearance by U.S. FDA

ImpediMed Limited (ASX.IPD) is pleased to announce clearance of SOZO® Pro, the company's next generation bioimpedance spectroscopy (BIS) system, by the U.S. Food & Drug Administration (FDA).

Key Points

- SOZO Pro offers a new, integrated weight scale, a higher standing weight capacity and an updated stand design allowing for easier transition between the standing and seated measurement positions.
- These changes will improve clinical workflow, allowing for greater scalability of the SOZO Digital Health Platform.
- The Special 510(k) FDA clearances cover substantial equivalence between SOZO Pro and SOZO for the lymphoedema and protein calorie malnutrition (body composition) indications.
- Achievement of this milestone clears the way to now submit a Traditional 510(k) application to the FDA for the heart failure indication, including removal of the contraindication for patients with pacemakers and implantable cardioverter-defibrillators (ICDs).

Focus on Private Payor Reimbursement in Lymphoedema

- With the recently announced update to the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Survivorship, which now includes bioimpedance spectroscopy, the Company's immediate focus remains on the expansion of private insurance reimbursement coverage of SOZO testing for breast cancer-related lymphoedema. SOZO and SOZO Pro are the only FDA cleared devices for bioimpedance spectroscopy[i].
- Private Payor Reimbursement is the first catalyst for expansion opportunity within the oncology market both in cancer-related lymphoedema and other aspects of survivorship.
- Then, once launched, SOZO Pro will further help accelerate expansion in oncology and, with removal of the contraindication for pacemakers and ICDs, will be crucial to additional markets such as heart failure.
- The current expectation for SOZO Pro launch timing is the 2024 fiscal year.

"FDA clearance of SOZO Pro is an important milestone in our product development and regulatory strategy," commented Richard Valencia, Managing Director and CEO of ImpediMed. "It offers several new features which will improve clinical workflow and expand SOZO testing to more patients. We continue to drive improvements in our product offering both with the SOZO system and its software to enhance the customer experience and further keep ourselves well ahead of any potential competition."

About SOZO Pro

SOZO Pro is ImpediMed's newest BIS system that provides personalised health metrics to quickly and reliably inform clinical decisions at the point of care. Compared to SOZO, SOZO Pro offers a new, integrated weight scale, a higher standing weight capacity (SOZO: 170 kg; SOZO Pro: 220 kg), and an updated stand design allowing for easier transition between the standing and seated measurement positions. These changes will improve clinical workflow and minimise data entry errors by making it even faster to take a BIS measurement. The higher weight capacity and pending removal of the contraindication for pacemakers and ICDs will make SOZO testing available to more patients.

Approved for release by the Managing Director & CEO, 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.

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.

[i] SOZO and SOZO Pro are the only FDA cleared devices for lymphoedema that utilise bioimpedance spectroscopy. ImpediMed's U400 device is also FDA cleared but is no longer commercially available.