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ASX ANNOUNCEMENT

FDA Grants Breakthrough Device Designation for Renal Failure

ImpediMed Limited (ASX.IPD) is pleased to announce SOZO has received FDA Breakthrough Device Designation for a proposed indication in a renal patient population.

ImpediMed intends to use its well-established SOZO bioimpedance spectroscopy (BIS) platform to provide an exact measure of fluid volume to remove during a dialysis session. The current process, utilising weight scales to determine accumulation of fluid, has significant deficiencies. The scales cannot account for changes in body composition, with muscle loss being prevalent in end-stage renal disease patients. The potential for SOZO to address this deficiency was paramount in meeting the criteria for Breakthrough Designation.

The US Breakthrough Device Designation is granted when a device is shown to meet the following criteria:

- The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions
- The device must also meet one or more of the following criteria:
    - Represents breakthrough technology
    - No approved or cleared alternatives exist
    - Offers significant advantages over existing approved or cleared alternatives
    - Device availability is in the best interest of patients

“Dry weight assessment and appropriate fluid removal during dialysis remains a significant challenge for nephrologists. Clinical assessment alone appears to be inadequate in many dialysis patients, especially those with multiple coexisting illnesses (cardiovascular disease, diabetes etc.). Both inadequate fluid removal and excessive fluid removal resulting in hypotension may adversely affect quality of life, increase hospitalisations and increase mortality,” commented Dr Mark M Boiskin MD FACP, Balboa Nephrology Medical Group & California Institute of Renal Research.

“A device that can quickly and easily be used in the dialysis setting to accurately measure fluid volume is currently not FDA approved and readily available. Such a device may significantly improve quality of care and improve patient outcomes,” he added.

There are many benefits associated with acceptance into the Breakthrough Program, with the FDA allocating specific resources throughout the development process to maximise the impact of the program. The benefits include:

- Interactive and timely communication
    - FDA provides interactive and timely communication during device development and throughout the review process.
- Efficient and Flexible Clinical Study Design
    - FDA collaborates to ensure the design of clinical trials is efficient and flexible.
    - This can include prespecified endpoints, the use of surrogate endpoints and adaptive study designs.

    - Importantly, the Breakthrough Program includes a provision for obtaining a binding agreement on clinical protocols.
- Priority Review
    - Breakthrough Devices receive priority review and
    - receive additional review resources, as needed.

The breakthrough designation positions ImpediMed to successfully expand its SOZO platform into the renal space. ImpediMed will partner with the FDA to expediate the development and clearance of SOZO. The breakthrough sprint sessions are the perfect forum to develop the clinical evidence plan, including trial design, to obtain data that will result in a successful clearance to market.

“We are extremely pleased to be moving forward with the renal opportunity through the FDA Breakthrough Device Program. There is a clear need for an innovative device to help clinicians more effectively manage end-stage renal disease patients. The mortality rate of these patients remains persistently high, with many dying from fluid related heart failure. We believe SOZO can provide a significant improvement to the dialysis process by better quantifying the volume of fluid needed to be removed,” commented Richard Carreon, Managing Director and CEO of ImpediMed. “It also allows us to advance the discussions with both potential clinical and commercial partners, with a goal of moving quickly to clinical trials and subsequently to commercialisation,” he added.

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.

About SOZO Digital Health Platform
SOZO, the world’s most advanced, noninvasive 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 lymphedema, provides fluid status for patients living with heart 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.