



30 September 2020

## ASX ANNOUNCEMENT

### AstraZeneca Selects SOZO for Heart Failure & Renal Trials

#### Key Highlights

- **AstraZeneca has selected SOZO to be used in a Phase II trial to measure fluid volume in patients with heart failure and chronic kidney disease.**
- **175 SOZO® devices will be leased across 20 countries for AstraZeneca trial.**
- **The trial will run for approximately 18 months and is expected to generate in excess of \$2 million in revenue.**

**Brisbane, Australia** – ImpediMed Limited (ASX:IPD), a medical software technology company that non-invasively measures, monitors and manages fluid status and tissue composition using bioimpedance spectroscopy (BIS), today announced a contract valued at over AUD \$2 million for its SOZO® Digital Health Platform to be used in a clinical trial being conducted for AstraZeneca, a global, science-led biopharmaceutical company. The Phase II trial will use the SOZO devices to track patient fluid volume in an upcoming pharmaceutical study focused on heart failure and chronic kidney disease. The study, which will begin in the second fiscal quarter and run for approximately 18 months, will require approximately 175 devices globally.

“AstraZeneca has used ImpediMed’s BIS technology for a number of years to measure subjects’ fluid volumes in their clinical studies,” stated Dennis Schlaht, Senior Vice President Research & Development and Technology of ImpediMed. “With SOZO, they will be able to achieve the fluid measurement accuracy of gold standard dilution methods in a test that takes 30 seconds instead of up to 24 hours. Add in the fact that it offers real-time data review globally, and it’s clear why the SOZO Digital Health Platform was chosen for this new research.”

The AstraZeneca study using SOZO will evaluate the efficacy, safety, and tolerability of a combination of two AstraZeneca drugs in heart failure patients with chronic kidney disease. This Phase II trial is scheduled to begin in November 2020. The trial is being run by a contract research organisation on behalf of AstraZeneca.

Under the terms of the agreement, and in alignment with the Company’s SaaS business model, each device will have a monthly license fee for the duration of the study. ImpediMed will retain ownership of the devices at the conclusion of the trials.

SOZO is FDA-cleared for heart failure and CE-Marked for heart failure and renal failure. The trial will provide a significant number of cardiologists, both in the US and globally, firsthand experience with SOZO and coincides with ImpediMed’s launch into the cardiology market. Cardiovascular disease is the leading cause of death among those with kidney disease. Among hospitalisations for primary heart failure, one of the most common comorbid diagnoses is chronic kidney disease (47%).

“We are extremely pleased that AstraZeneca decided to use our BIS technology again in this clinical trial,” commented Richard Carreon, Managing Director and CEO of ImpediMed. “Heart failure and chronic kidney disease are two of our three strategic focus areas, and this agreement provides further validation of the applicability of our technology in both patient populations. This endorsement of our technology is timely as the Company begins the launch of SOZO into the cardiology market.”

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 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](http://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/>

## About SOZO Fluid Analysis for Heart Failure

The SOZO fluid analysis for heart failure provides an objective measure of fluid overload in heart failure patients. It utilises ImpediMed's HF-Dex™ heart failure index which is a measure of extracellular fluid as a percent of total body water. HF-Dex is presented on BIS-derived reference ranges which indicate normal fluid volumes, elevated fluid volumes, and fluid overload, which is defined as HF-Dex greater than 51%. When used as part of a clinical assessment of heart failure, SOZO helps differentiate between fluid and tissue-related weight changes to track response to medication changes and to provide a marker for readmission when HF-Dex is higher than 51%.

For more information, visit: <https://www.impedimed.com/healthcare/heart-failure/>

### **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.