11 February 2022

**ASX ANNOUNCEMENT**

**ImpediMed Announces a Clinical Trial Agreement for its SOZO Platform in Patients with End Stage Renal Disease (ESRD)**

ImpediMed Limited (ASX.IPD) is pleased to announce it has entered into an agreement with balboa RESEARCH SMO+ ("Balboa") and Frenova Renal Research, a Fresenius Medical Care Company, to conduct an initial Observational Trial. The Company is also very pleased to announce that Dr Mark Boiskin and Dr Dylan Steer have agreed to serve as Principal Investigators for both the Observational Trial and a pivotal Interventional Trial, which will be used to support an FDA clearance for renal failure.

The Company is very fortunate to collaborate on this Observational Trial with these two industry leading nephrologists. Both Dr Boiskin and Dr Steer are driven to provide better patient outcomes and are advocates of the SOZO platform. They see the compelling potential for the SOZO platform to accurately measure and determine the optimal amount of fluid to remove during dialysis. ImpediMed has leveraged their expertise in the design of the Observational Trial. The Observational Trial will be conducted across three (3) Balboa Nephology and Fresenius Medical Care joint venture dialysis centres.

The primary goal of the Observational Trial is to assess the applicability of the SOZO platform in a dialysis setting and collect data that can be used to refine the protocol for an Interventional Trial. The Observation Trial will enroll approximately 70 patients who will be followed over 4 weeks and 12 dialysis sessions. The Company expects the trial to commence upon IRB approval, in late February, and to be completed in Q4 FY'22.

Additionally, the Company, together with Dr Boiskin and Dr Steer, will shortly commence discussions with the FDA as a part of the Breakthrough Device Designation process. These discussions will determine the Interventional Trial clinical evidence plan, including trial design, protocols, and relevant end points that would position SOZO for potential market clearance. Current expectations are for the Interventional Trial to commence in Q1 FY'23 with more details to be announced post the completion of discussion with the FDA.

**About the Principal Investigators**

Dr. Dylan Steer serves as President, Value Based Care for Balboa Nephrology Medical Group in San Diego, where he leads a group of 60 physicians and providers who are focused on consistently delivering superior care to every patient with kidney disease. Dr. Steer has over 15 years of experience in clinical research across drug, device and diagnostics, including Phase 1a-IV. He is a recognised expert in renal disease, particularly in CKD 2-5 and ESRD.

Dr. Steer notes that, "the current process of using weight scales to determine accumulation of fluid has significant deficiencies. Patients and caregivers would benefit from more accurate technologies." He continues, "in particular, recognising changes in body composition and muscle loss, an ongoing problem for ESRD patients, could benefit from the SOZO platform. We see tremendous potential in the SOZO platform to address this unmet need. We are excited to initiate the Observational Trial of the SOZO platform that has been granted Breakthrough Device Designation by the FDA."

Mark Boiskin, MD, FACP is a practicing nephrologist at Balboa Nephrology Medical Group and is affiliated with multiple hospitals in the San Diego area, including Scripps La Jolla and Scripps

Encinitas Hospitals. He has served as Chairman of Pharmacy and Therapeutics and Chairman of Medicine at the Scripps Memorial Hospital. He is dedicated to advancing renal research with over 18 years of clinical research experience with drug, device, and diagnostics in Phase Ia-IV. Dr. Boiskin is active in educational outreach, giving presentations to patients on the latest treatments in nephrology for CKD and ESRD patients.

"Dry weight assessment and appropriate fluid removal during dialysis remains a significant challenge for nephrologists," said Dr. Boiskin. "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. A device that can quickly and easily be used in the dialysis setting to accurately measure fluid volume is currently not FDA approved, though the technology is readily available. Such a device may significantly improve quality of care and improve patient outcomes," he added.

**About balboa NEPHROLOGY and balboa RESEARCH SMO+**

For nearly 50 years, balboa NEPHROLOGY has grown from two physicians to a comprehensive nephrology team of 52 board certified physicians and 8 advanced care practitioners and is a recognized leader in quality, outcomes and value-based care. balboa's patient centric footprint consists of 24 clinical offices, 88 dialysis clinics throughout San Diego, Imperial and Orange Counties. Balboa NEPHROLOGY manages over 40,000 patients in their clinics and over 4,200 ESRD patients. (https://balboacare.com/)

balboa RESEARCH SMO+ (formerly the California Institute of Renal Research) is a wholly owned subsidiary of balboa NEPHROLOGY consisting of 10 Principal Investigators, 23 dedicated research staff across 6 fully equipped research sites in San Diego and Imperial Counties. Over nearly 20 years, balboa RESEARCH SMO+ leverages its scope, scale, and affiliation with balboa NEPHROLOGY to collaborate early with pharmaceutical and medical device sponsors on cutting edge therapeutics and diagnostics. (https://balboacare.com/balboa-research/)

**About Frenova**

Frenova, a Fresenius Medical Care Company, provides sponsors with the most suitable investigators and patients to achieve enrollment goals for renal or adjacent disease trials. As a site management organization with over 25 years of experience centered on renal research and the unique needs of renal patients, Frenova provides managed investigator sites, patients, and the data for clinical trial demands. Frenova's partnership with Fresenius Medical Care provides unmatched and exclusive access to renal expertise and global patient population, facilitating rapid clinical research, patient recruitment and enrollment for trials.

**ImpediMed Managing Director and CEO comment**

"We are extremely pleased to be moving forward with the renal opportunity with such credentialed partners. 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.

**Approved for release by the Managing Director and CEO, Mr. Richard Carreon.**

**Contact Details**

**Investor relations Contact:**
Mike Bassett, ImpediMed
SVP Corporate and Strategic Development
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 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.

**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.