



12 October 2022

## ASX ANNOUNCEMENT

### **Clinical Update: NCCN Submissions, HSFA Posters, Lymphoedema & Sarcopenia Publications**

ImpediMed Limited (ASX:IPD) is pleased to provide an update covering recent developments in the Company's clinical program. Additional publications and data continue to expand the body of literature across all areas of the business and overwhelmingly support the need for the Company's proprietary bioimpedance spectroscopy (BIS). In particular, the recent lymphoedema publications continue to advance the support of BIS in prospective surveillance and in providing further evidence for Private Payor reimbursement submissions.

#### **Key highlights include:**

##### **NCCN**

1. NCCN Guidelines® Update: In addition to the two submissions currently under review by the Breast Cancer Panel, a third submission has been made to the NCCN Survivorship Panel for review at their annual Panel Meeting.

##### **Oncology**

2. Lymphoedema Publications:
  - i. PREVENT Secondary Aims paper published in *Lymphatic Research and Biology*.
  - ii. A systematic literature review of the latest publications supporting screening and early intervention" published in *Journal of Cancer Survivorship*.
3. Broader Oncology Publications: Two papers studying the effects of sarcopenia detected by SOZO® in breast cancer patients published:
  - i. Analysis of the impact of BIS-detected sarcopenia on chemotherapy-related toxicity in early-stage breast cancer patients and correlation to computed tomography (CT) scan published in *Breast Cancer*.
  - ii. Analysis of the impact of BIS-detected sarcopenia on endocrine therapy-related toxicity in early-stage breast cancer patients published in *Breast Cancer*

##### **Heart Failure**

4. Heart Failure Presentations: Two posters presented at the 2022 Annual Heart Failure Society of America Meeting.

#### **Detailed Update:**

##### **1. NCCN**

- i. Survivorship Panel submission

A new submission has been made by a leading healthcare system to the NCCN Survivorship Panel, ahead of its annual meeting that will be held over two days on 19 and 26 October, 2022.

The Survivorship Guidelines play a critical role in the ongoing treatment of cancer survivors. They encompass all cancer types and broaden the application of any treatment specified. They are often

specifically referenced within the cancer specific guidelines, as is the case with the NCCN Breast Cancer Guidelines.

The Survivorship Guidelines currently contain comprehensive lymphoedema treatment guidelines. This additional NCCN submission looks to augment the guidelines by recommending survivors should be followed as part of a prospective surveillance model of care, with an objective tool such as bioimpedance spectroscopy (BIS), to detect the earliest signs of lymphoedema.

ii. NCCN Breast Cancer Panel submissions

The Company understands that the two independent submissions presented at the Annual Breast Cancer Panel meeting, held on 25 and 26 August, 2022, have been reviewed and the expectation remains that any changes will be published by the end of the calendar year.

## 2. Lymphoedema Publications

Recent lymphoedema publications continue to expand the body of literature that overwhelmingly support the need for BIS in prospective surveillance and provides further evidence for commercial health plan reimbursement submissions. Quality of life is pertinent to commercial health plans as reducing the mental health burden is a key focus for overall care. The systematic review has also proved to be constructive demonstrating BIS as a cost effective and practical method to monitor patients.

- i. PREVENT Secondary Aims Paper titled “Prospective Surveillance with Compression for Subclinical Lymphedema: Symptoms, Skin, and Quality-of-Life Outcomes” published in *Lymphatic Research and Biology*.

New data from the PREVENT trial, the largest randomised trial to assess lymphoedema prevention, titled was published in *Lymphatic Research and Biology*. The paper confirms that early detection and intervention of breast cancer-related lymphoedema improve quality of life by reducing the burden of chronic lymphedema on patients. In addition, the paper demonstrated that L-Dex<sup>®</sup> testing is more effective than tape measure at identifying the optimal time to intervene to stop lymphoedema progression.

A link to the manuscript can be found here:

<https://www.liebertpub.com/doi/10.1089/lrb.2022.0020>

- ii. Systematic review titled “Reducing rates of chronic breast cancer-related lymphoedema with screening and early intervention” published in *Journal of Cancer Survivorship*.

This paper supports BIS L-Dex as the method of monitoring patients at risk of breast cancer related lymphoedema (BCRL). The paper concluded “that although there are several methods that can be used to monitor and screen patients, this literature review of recent data supports BIS as a cost effective, practical, and reproducible method for this purpose with level I data documenting statistically superior, clinically meaningful reductions in the irreversible and chronic form of BCRL compared to circumference/tape measurements”.

A link to the manuscript can be found here:

<https://link.springer.com/article/10.1007/s11764-022-01242-8>

### 3. Broader Oncology (Sarcopenia) Publications

Cleveland Clinic physicians have authored two papers demonstrating the potential utility of the SOZO Digital Health Platform, as the company continues to explore new indications within oncology.

- i. Sarcopenia detected with bioelectrical impedance versus CT scan and chemotherapy tolerance in patients with early breast cancer, published in Breast Cancer

The study utilised SOZO BIS readings, generating the following results:

- 28% (n=323) of patients had sarcopenia as assessed by BIS (defined as skeletal muscle index  $\leq 6.75$  kg/m<sup>2</sup>)
- There was a correlation between CT scan and BIS-detected sarcopenia,  $r=0.64$ ,  $p<0.0001$
- Patients with BIS-detected sarcopenia had higher odds of the following outcomes compared to patients without sarcopenia:
  - Chemotherapy toxicity (OR 2.56 95% CI 1.72–3.84  $p < 0.0001$ )
  - Dose reduction or dose delay due to side effects (OR 1.58 95% CI 1.06–2.38  $p = 0.02$ )
  - Hospitalisations (OR 2.38 95% CI 1.33–4.16  $p < 0.004$ )
  - Neuropathy (OR 2.32 95% CI 1.42–3.7  $p = 0.0006$ )

The authors conclude that BIS as an effective means of assessing sarcopenia and BIS-assessed sarcopenia appears to be a potentially modifiable risk factor for poor tolerance of chemotherapy in early breast cancer patients.

A link to the manuscript can be found here:

<https://link.springer.com/article/10.1007/s12282-022-01401-w>

- ii. Association of sarcopenia with endocrine therapy toxicity in patients published in Breast Cancer Research and Treatment.

This second study showed:

- Overall, 12% of patients experienced high grade endocrine-related toxicities.
- Patients with sarcopenia had more endocrine therapy toxicity (17% vs 10%  $p = 0.01$ ).
- The presence of sarcopenia was associated with a significant increase in the odds of experiencing endocrine-related toxicity compared to those without sarcopenia (OR 2.44 95% CI 1.29–4.62,  $p = 0.006$ ).
- Early treatment change or discontinuation due to side effects was observed in 13% of the cohort.
- Patients with sarcopenia stopped or changed their medication due to side effects more often than those without sarcopenia (OR 2.00 95% CI 1.07–3.73  $p = 0.03$ ; Table 3).

The strengths of the study include the size of the cohort and the use of BIS rather than CT scans to screen for sarcopenia. The authors stated that BIS is a reliable, inexpensive, easy-to-use, radiation-free technique and provides the skeletal muscle mass (SMM) immediately with potential for real-time use in clinical decision making.

A link to the manuscript can be found here:

<https://link.springer.com/article/10.1007/s10549-022-06741-x>

#### **4. Heart Failure Presentations**

Two posters presented at the 2022 Heart Failure Society of America (HFSA) Annual Scientific Meeting demonstrating the utility of the SOZO Digital Health Platform for Heart Failure Patients. The annual meeting took place 30 Sep to 3 Oct 2022 in Washington D.C.

The HFSA Annual Meeting draws experts on heart failure care with the goal of reducing the burden of heart failure through education, innovation, and research. It is a highly specialised scientific conference and one of the leading forums to present research in heart failure.

The following posters were presented:

- i. Bioimpedance Spectroscopy Distinguishes between Fluid Status in Individuals with and without Heart Failure

Three cohorts of patients including heart failure patients enrolled in a single center observational study and a multi-centre observational study led by researchers at Scripps Health in San Diego, California. The study evaluated one-time SOZO Digital Health Platform BIS measurements using ImpediMed's HF-Dex™ heart failure index of heart failure patients compared to non-heart failure patients. The results showed that BIS is able to differentiate between the two groups with 79.8% sensitivity and 79.7% specificity.

- ii. Bioimpedance Spectroscopy Derived Arm-to-Leg R0\_ratio as a Predictor of Increased Intravascular Volume and Need for Up-Dosing

The poster profiled a single-center observational study led by researchers at Scripps Health in San Diego, California evaluating fluid volume status of heart failure patients during a routine clinic visit with a heart failure specialist. The study analysed SOZO Digital Health Platform BIS measurements compared to the heart failure specialist's expert assessment of fluid volume and decision to adjust medication. The authors concluded that BIS enhances the ability to identify patients who have increased fluid volume and are likely to require increased diuretic dosing.

"Clinicians lack objective methods to evaluate fluid volume in heart failure patients leading to suboptimal medical management and increased risk of decompensation, which can lead to hospitalisation," commented Dr. Andrew Accardi, Emergency Medicine Physician at Scripps Health in San Diego, California and coauthor on both posters. "These studies add to the growing evidence that BIS provides an objective assessment of fluid volume to help track changes in heart failure patients and potentially guide medical intervention," he continued.

A summary of these developments in the Company's clinical program will be provided at the Company's upcoming quarterly investor call.

**Approved for release by Interim CEO, Mr. David Anderson.**

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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).

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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.

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