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ASX/MEDIA RELEASE

IMPEDIMED ANNOUNCES SCIENTIFIC MEETING REVIEW BY LEADING US HEALTHCARE INSURER

ImpediMed Limited (ASX: IPD) today announced that CMS, the largest insurer of US healthcare, has called for a MEDCAC meeting on November 18th, 2009 to review the management of secondary lymphoedema – this would likely involve a review of the technology used in ImpediMed’s FDA cleared, flagship product, the L-Dex™ U400.

“CMS is the Centers for Medicare & Medicaid Services. Formerly known as the Health Care Financing Administration (HCFA), it is the federal agency responsible for administering the Medicare, Medicaid, CHIP (Children’s Health Insurance), HIPAA (Health Insurance Portability and Accountability Act), CLIA (Clinical Laboratory Improvement Amendments), and several other health-related programs.” [http://www.cms.hhs.gov/]

“CMS insures around 28% of the US population, which translates into 83 million people, covered by US government programs. A MEDCAC meeting reviews the available scientific support for adopting a new technology or treatment or both. It is an important step that can significantly advance the adoption of state of the art healthcare. A positive MEDCAC meeting may lead to local carrier coverage or a US national coverage statement, for the use of a medical device or treatment,” said Mr Greg Brown CEO of ImpediMed. He went on to say that, “The Company has a core focus on lymphoedema prevention being firmly part of the healthcare agenda for all patients globally. Awareness and education are two very important steps to address this condition appropriately. We feel that L-Dex™ devices can aid surgeons, radiologists, oncologists and therapists secure pre-operative and postoperative clinical surveillance to help prevent the progression of this disorder. A national coverage statement, or local carrier coverage, around the use of a device for aiding in the clinical assessment of lymphoedema could have a very positive impact, ensuring patients are treated prospectively. Company revenues are directly tied to effective reimbursement, so the importance of any meetings that can lead to coverage can be significant.” In closing Mr Brown stated, “We did not think that the opportunity for a MEDCAC meeting would occur until well into 2010, the fact it is occurring now is exciting. Today we believe the clinical data for unilateral arm applications to be sufficient to support a positive clinical evidence review for breast cancer patients.”
“The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) was established to provide independent guidance and expert advice to CMS on specific clinical topics. The MEDCAC is used to supplement CMS' internal expertise and to allow an unbiased and current deliberation of "state of the art" technology and science. The MEDCAC reviews and evaluates medical literature, technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered under Medicare, or that may be eligible for coverage under Medicare. The MEDCAC judges the strength of the available evidence and makes recommendations to CMS based on that evidence.”

“CMS has called for a MEDCAC meeting on November 18th, 2009, for the panel to discuss the adequacy of the available evidence that supports the diagnostic and treatment methods used in the management of secondary lymphedema. Medicare currently has a national coverage determination for the use of lymphedema pumps related to the treatment of this condition.”

“In the United States, the most common form of secondary lymphedema is that associated with the surgery and radiation of cancer treatment……. Strategies for the treatment of secondary lymphedema are directed at preventing or minimizing the fluid accumulation in the affected body parts, restoring any lost function and providing education to avoid the potential of anticipated complications.”


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L-DexTM is a trademark of ImpediMed Limited.

* L-Dex™ values that lie outside the normal range may indicate the early signs of lymphoedema and values that have changed +10 L-Dex units from baseline may also indicate early lymphoedema. The L-Dex scale is a tool to assist in the clinical assessment of lymphoedema by a medical provider. The L-Dex scale is not intended to diagnose or predict lymphoedema of an extremity”.

About ImpediMed
ImpediMed Ltd. is the world leader in the development and distribution of medical devices employing Bioimpedance Spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of fluid status. ImpediMed’s primary product range consists of a number of medical devices that aid surgeons, oncologists, therapists and radiation oncologists in the clinical assessment of patients for the potential onset of secondary lymphoedema. Pre-operative clinical assessment in breast cancer survivors, before the onset of symptoms, may prevent the condition from becoming a lifelong management issue and thus improve the quality of life of the cancer survivor. ImpediMed had the first medical device with an FDA clearance in the United States to aid health care professionals, clinically assess secondary lymphoedema of the arm in female breast cancer patients. For more information, visit. www.impedimed.com.