



21 November 2011

## **Sphere Medical Holding plc**

### **Clinical Trial on Proxima Generation 2 Successfully Meets Endpoints**

Cambridge, UK, 21 November 2011: Sphere Medical Holding plc (AIM:SPHR.L) ("Sphere Medical" or the "Company"), a leading developer of innovative monitoring and diagnostic products for the critical care setting, is pleased to announce that its clinical trial on Proxima Generation 2 has met its primary endpoint to demonstrate equivalent performance to laboratory and Point of Care blood gas analysers measuring arterial blood in a clinical setting.

Seventeen patients were included in the clinical trial and 100 samples were taken. The trial was conducted in the Operating Theatre and Intensive Care Unit at both the Queen Elizabeth Hospital, Birmingham (one of the largest ICU centres in Europe) and the West Suffolk Hospital.

The Proxima system is based on Sphere Medical's proprietary microanalyser platform technology, which has previously been demonstrated in the first generation 510(k) cleared *in-vitro* bench top analyser. Proxima Generation 2 is Sphere Medical's first patient-attached arterial blood analyser, drawing blood from an arterial line for analysis before flushing to waste; this facilitates the near real time analysis, with laboratory accuracy, of a patient's arterial blood with output data being displayed on a bedside monitor. In addition to meeting its primary endpoint, the device has shown itself resilient to use in the critical care environment, including during diathermy. The device was demonstrated to be useable for repeated measurements of blood without requirement for anticoagulation and without deterioration in performance.

The Company intends to CE Mark Proxima Generation 2 before the end of 2011.

Commenting on the Proxima Generation 2 clinical trial, Chief Executive Officer, Dr Stuart Hendry, said:

*"The success of this trial is a major milestone achievement for Sphere Medical. We have demonstrated that Proxima will be able to deliver rapid and convenient measurement of blood chemistry in a critical care setting without compromising analytical accuracy, equivalent to the current standard of care. The information Proxima provides should assist clinicians to enhance patient care and improve outcomes."*

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### Notes for Editors

Sphere Medical is a UK based medical device company completing the development of a range of monitoring and diagnostic products designed to provide significant improvements in patient management in a number of hospital specialities. Sphere Medical's products are expected to allow near real time measurement of blood gases, various electrolytes and drug levels with laboratory accuracy, at the patient's bedside. This information can be used in a wide range of medical applications and is intended to enable faster clinical decision making and consequently to improve the management of patients.

Sphere Medical's two most advanced products, based on its proprietary microanalyser platform technology, are a disposable patient-attached arterial blood analyser for use in the Intensive Care Unit and Operating Room ('**Proxima**') and a device for continuous blood monitoring in the bypass circuit in patients undergoing cardiopulmonary bypass surgery ('**CPB device**'). Sphere Medical has also developed and is selling a device ('**Pelorus 1000**') that can measure blood levels of the intravenously administered anaesthetic drug, propofol. In each case, these products will ultimately target patients requiring close monitoring and frequent levels of blood testing.

Sphere Medical employs 43 staff in the areas of research and development, product development, sales and marketing and management and operations at its premises at Harston, Cambridge, UK.