GLYSURE SECURES CE MARK AND LAUNCHES WORLD'S FIRST CONTINUOUS INTRAVASCULAR GLUCOSE MONITORING SYSTEM

System addresses unmet need for continuous glucose monitoring in the ICU, a potential market in excess of $5 billion

ABINGDON, England, July 1, 2015 – GlySure Limited today announced that it has secured the CE Mark for the world's first and only Continuous Intravascular Glucose Monitoring System (CIGMS). The initial use of the GlySure™ CIGMS is to enhance blood glucose management among adult cardiac surgery patients in the Intensive Care Unit (ICU). The need for enhanced glucose management exists within all critical care settings.[1,2] GlySure is currently conducting a UK-based multicentre trial designed to enable use of the GlySure CIGMS across all adult Intensive Care patients.

In critically ill patients, poorly controlled blood sugar levels can lead to increased mortality, morbidity, lengths of stay in the ICU and costs to healthcare providers.[3] This CE Mark clears the path for GlySure to market its GlySure CIGMS in Europe. The Company will first bring this solution to leading critical care centres in the UK, Benelux and Germany, followed by launches in additional European countries and other markets where CE Mark is recognised.

"For over a decade, the clinical community has been seeking a way to tightly control glucose levels in critically ill patients for both improved outcomes and reduced costs," said Dr. Krishna Prasad, MD FRCA CCST, Consultant Anaesthesiologist at Care Hospitals, Nampally in Hyderabad, India, who was the Principal Investigator of the CIGMS CE marking trial. "GlySure's technology enables them to do this safely with accuracy, reliability and efficiency to support the implementation of improved Glycaemic Control protocols."

"We are pleased to bring to market the first practical solution to address this significant unmet medical need," said Roger Moody, Chief Operating Officer for GlySure. "Our first customers will lead the way in how glucose management is best practised, enabling improved patient outcomes and reduced healthcare costs. Continuous glucose monitoring in critical care has been a vexing medical challenge. GlySure's game changing technology and elegant CIGMS solution will be the first in this market to deliver clinical value to patients and savings to healthcare providers."

GlySure received its CE Mark following a review of its submission that included the results of its multicentre clinical trial that demonstrated the system's ability to provide accurate continuous blood glucose monitoring in patients throughout their length of ICU stay. The GlySure CIGMS met the primary safety and efficacy endpoints and demonstrated a consistently high level of accuracy compared to a "gold standard" intermittent glucose analyser.

The GlySure CIGMS comprises of three main parts: a monitor, a disposable fibre optic sensor and a disposable 5 lumen central venous catheter (CVC), similar to that typically used in the ICU. The GlySure sensor includes a highly selective proprietary chemistry that provides the first commercially available glucose testing system that can accurately measure intravascular glucose levels every fifteen seconds. This breakthrough provides physicians with continual feedback that helps avoid dangerous fluctuations in ICU patient glucose levels.

GlySure intends to seek clearance from the U.S. Food and Drug Administration (FDA) for the GlySure CIGMS and is currently finalising the design of the clinical trial to support its submission. The Company has recently appointed Albert Leung, MD PhD as its Chief Medical Officer who will lead these clinical and regulatory efforts. Dr. Leung is an endocrinologist with 20 years of clinical practice and industry experience, and had previously worked at Merck and Johnson & Johnson to bring new products to market by leading their clinical development programs.

GlySure estimates the global market opportunity for continuous glucose monitoring in the ICU is greater than $5 billion. This calculation takes into consideration the total number of patients in a critical care setting worldwide.

About GlySure:

GlySure is leading the way towards improved glycaemic control. As the first to market with a continuous intravascular glucose monitoring system (CIGMS), the Company is enabling critical care physicians to provide improved glycaemic control that has been shown to improve patient outcomes while reducing risk to patients and reducing cost for healthcare providers. The worldwide market opportunity for CIGMS is greater than $5 billion. Continuous glucose monitoring beyond the ICU in hospitals is an even larger market opportunity that could also be addressed by GlySure's technology. The Company has demonstrated through ICU testing that its highly accurate GlySure CIGMS provides continuous glucose readings throughout the length of a patient's stay in the ICU, and in some cases, beyond. For more information, visit www.glysure.com.

About Glycaemic Control:

Glycaemic control has been an important indicator for acute care patients for decades. In 2001, Greet Van den Berghe demonstrated that controlling patient glucose levels in the ICU within tight normal ranges yielded significant improvements in patient outcomes, including a 46 per cent reduction in incidence of sepsis, 41 per cent reduction in renal failure, 50 per cent reduction in blood transfusions and 34 per cent reduction in mortality.[1] This study created a new field of medical research with over 100 publications in the past decade including two showing a financial benefit to the hospital in savings of $1,580 and €2,638 per patient, respectively.[3,4] More recently, the NICE-SUGAR trial provides evidence that patients have better outcomes when glucose levels are higher and hypoglycaemia events are lower.[5] Regardless of the debate over the most appropriate target glycaemic range, clinicians are best prepared to reduce the risk of hypo- and hyper-glycaemic events with the availability of continuous glucose monitoring.

About CE Mark:

The CE Mark certificate denotes that all regulatory requirements of applicable EU Directives for medical devices have been met – effectively clearing products for commercialisation in the European Economic Area, including the United Kingdom.

For further information, please contact:

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References:

1. Van den Berghe G, et al. Intensive Insulin Therapy in Critically Ill Patients. *N Engl J Med.* **345**, 1359–1367 (2001).
2. Krinsley JS, Preiser J. Time in blood glucose range 70 to 140 mg/dl >80% is strongly associated with increased survival in non-diabetic critically ill adults. *Critical Care.* **19,** 179 (2015).
3. Krinsley JS, Jones RL. Cost analysis of intensive glycemic control in critically ill adult patients. *Chest.* **129(3)**, 644-650 (2006).
4. Van den Berghe G, et al. Analysis of healthcare resource utilization with intensive insulin therapy in critically ill patients. *Crit Care Med*. **34(3)**, 612-6 (2006).
5. The NICE-SUGAR Study Investigators. Hypoglycemia and risk of death in critically ill patients. *N Engl J Med.* **367**, 1108-1118 (2012).