CMR Surgical successfully completes first set of robotically assisted surgical procedures in humans

Versius surgical robotic system successfully used to complete 30 procedures at leading hospital in India.

CAMBRIDGE, UK. 13 May 2019. CMR Surgical Ltd, the company behind the next-generation surgical robotic system Versius®, today announced that it has successfully completed its first series of surgical procedures in humans.

30 laparoscopic procedures were completed as part of a clinical trial at Deenanath Mangeshkar Hospital & Research Center in Pune, India, by Consultant Oncologist and General Surgeon Dr. Dhananjay Kelkar and his team. The surgeries consisted of minor, intermediate and major gynaecological and upper gastrointestinal (GI) procedures. No adverse events were reported as a result of the use of Versius after a 30 day follow up.

“As the first surgeon to conduct a laparoscopic procedure in a clinical setting using Versius, I can say that the system has been shown to be highly effective and has significant potential for bringing minimal access surgery to patients here in India, and around the world. The Versius® Surgical Robotic System is flexible and fits easily into our busy operating environment. We have a high demand for surgical care and are committed to bringing the most innovative technologies to our patients,” commented Dr. Dhananjay Kelkar.

“This first-in-human series is a significant milestone in bringing Versius to operating theatres around the world. These initial results are positive and we look forward to further advancing our mission to bring the benefits of minimal access surgery to everyone who needs it. This series is part of our drive for the responsible introduction of surgical robotic systems that puts safety and effectiveness above all else,” commented Mark Slack, Chief Medical Officer at CMR Surgical.

The clinical trial was conducted in line with CMR Surgical’s collaboration with the IDEAL framework which provides an international benchmark for each stage of the surgical innovation process, including clinical trials. The first-in-human series is being carried out under internationally recognised clinical trial protocols as set out by Good Clinical Practice (GCP).

The company received a European CE Mark in March for the Versius® Surgical Robotic System.

Following the completion of the first-in-human series, CMR Surgical will work closely with surgeons and hospitals on a clinical introduction of the Versius® Surgical Robotic System to bring the benefits of minimal access surgery to patients around the world.
Notes to editors:

About Deenanath Mangeshkar Hospital & Research Center, Pune, India.

Deenanath Mangeshkar Hospital & Research Center is a charitable, multi-specialty hospital located in Pune, India. The hospital was founded in 2001 and is one of the largest hospitals in Pune, with over 800 beds. The hospital was founded by The Lata Mangeshkar foundation that was established in October 1989, by the Mangeshkar family that is renowned in the field of music in India. The foundation collaborated with the Jnana Prabodhini Medical Trust to establish the hospital with the commitment that everyone receives access to high quality healthcare.

The Versius Clinical Study

The Versius Clinical Study is a single-centre, prospective cohort study. The study design is to evaluate the safety and performance of Versius in robotically-assisted surgery across a range of abdominal and pelvic surgical procedures. The primary endpoint of the study is the rate of unplanned conversion of procedures to other minimal access surgery or open surgery. Secondary outcomes collected are, operative time; estimated blood loss and blood transfusion rate, intra-operative complications; return to operating room within 24 hours; length of hospital stay; and readmission to hospital within 30 days of surgery. Ninety-day mortality statistics will be collected. The performance of Versius will be assessed continuously throughout the study and any problems with the system will be monitored and reported.

The results of this study will be included in the CMR Surgical Registry. This is a prospective real-world data registry, set up to gather clinical performance and safety data on all surgical procedures conducted with the Versius® Surgical System in all geographical locations. In addition to providing post-market safety data it will also allow monitoring of individual surgical performance.

The Versius® Surgical Robotic System

Versius® resets expectations of robotic surgery by providing a versatile system that is portable, transportable and affordable. This is made possible because of its elegant form factor, modular design and individually cart-mounted arms. Versius® is able to move between operating rooms and even hospitals/clinics and gives the surgical team excellent access to the patient at all times.

Biomimicking the human arm, Versius® allows surgeons the freedom of port placement, but with the benefits of small fully-wristed instruments. With 3D HD vision, easy-to adopt instrument control and a choice of ergonomic working positions, the new open surgeon console has the potential to reduce stress and fatigue and extend the careers of surgeons.
About CMR Surgical Limited

CMR Surgical is a British private limited company developing the next-generation universal robotic system, Versius®, for minimal access surgery. The company received the European CE Mark in March 2019 for the Versius® Surgical Robotic System.

The vision behind CMR Surgical is to make minimal access surgery universally accessible and affordable, transforming the existing market for surgical robotics while also addressing the six million people who still undergo open surgery each year.

Global annual revenues for robot-assisted minimal access surgery are presently approximately $4 billion and are anticipated to reach $20 billion by 2025.

CMR Surgical, formed in 2014, has its headquarters in Cambridge, United Kingdom and is backed by an international shareholder base of specialist and generalist investors.

The Company achieved the registration of its Quality Management System to ISO 13485:2016 by Underwriters Laboratories LLC® (UL), and the status as a UL Registered Firm, in September 2015.

For further information, please visit www.cmrsurgical.com