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Optiscan Trial update: Trials underway in four continents with successful commencement of USA trials.

Doctors at the University of Pittsburgh Medical Center (UPMC) have commenced patient studies as part of the Pentax sponsored trials of Optiscan's flexible endo-microscope technology.

The trials now span four continents through leading teaching hospitals:

- Cabrini Hospital, Melbourne, Australia
- University Hospital, Mainz, Germany
- University Hospital, Kyushu, Japan
- University of Pittsburgh Medical Centre, Pittsburgh, USA

The trials support Pentax's global sales release of the flexible endo-microscope system anticipated in the first half of 2004.

"We are pleased to have our technology being used in trials by pre-eminent physicians from leading hospitals in each of the critical markets around the globe," said Matthew Barnett, CEO, Optiscan.

Focus of UPMC Trials

The University of Pittsburgh Medical Center (UPMC) is one of the top ten hospitals in the USA. It is highly regarded for its medical research into new and innovative gastrointestinal procedures.

The initial focus of the UPMC trial is assessing a unique application of the technology in the endoscopic surveillance of patients who have undergone small bowel transplants. The trial will investigate the capability of the new endo-microscope to provide a method of diagnosing early danger signs of transplant rejection without the need for a biopsy.

Using the flexible endo-microscope doctors will look for microscopic signs of tissue rejection in transplanted small bowels. Presently, transplant patients undergo frequent medical procedures where biopsies (surgically removed tissue samples) are taken from the transplanted organ.

The second component of the study will evaluate the use of the endo-microscope to describe microscopic evidence of diseases requiring surgical removal of the bowel. Doctors hope that this component of the study will help to define the relationship between the microscopic images produced by the instrument and specific disease states requiring medical intervention.

Dr Rocky Schoen, chief investigator of the UPMC trial, said, "We are delighted that Pentax has chosen UPMC to be the first hospital in the USA to have access to this new endo-microscope technology."

Trial Program Overview

Optiscan and Pentax in consultation with leading gastroenterologists have identified key areas of medical need where the flexible endo-microscope has high potential to improve outcomes and lead to substantial uptake of the technology.

Each hospital involved in the Pentax sponsored trial program is investigating different applications, as follows:

- Australia: Colon cancer surveillance and monitoring of inflammatory bowel disease (ulcerative colitis and Crohn's disease).
- Germany: Monitoring of inflammatory bowel disease and improved colon cancer detection in combination with chromo-endoscopy techniques.
- Japan: Gastric cancer management.
- USA: Surveillance for signs of organ rejection in small bowel transplant patients and recognition of disease states requiring bowel removal.

In each of the applications being trialed, doctors are investigating the potential of microscopic imaging to improve patient outcomes in such common clinical problems as:

- Long-term repeat surveillance of patients
- Difficult to detect early stage disease
- Multiple biopsies normally required
 - time consuming
 - expensive
 - increased risk to patients
- Inadequate disease detection rates

"Our trial program features leading doctors working to address some of the really big issues in gastroenterology today.", said Peter Delaney, Optiscan's Director of Technology.

Preliminary results from several of these studies will be presented by the investigating doctors at the annual Digestive Diseases Week congress (DDW), the largest meeting of gastrointestinal endoscopists in the world, to be held in May in New Orleans, USA. Summary results (abstracts) will be published by the congress organisers in mid February 2004. The early results are expected to indicate the potential of the technology in several clinical applications and lead to further studies designed to measure advantages to patient care achievable with the endo-microscope. Optiscan expects that the preliminary trial results from Australia and Germany will provide the best indications of the potential of the technology as the trials featured the largest patient numbers.

The process of progressing to mainstream clinical adoption of Optiscan's flexible endo-microscope technology will include further confirmatory multi-centre studies to be conducted by teaching and research hospitals.

Background

Optiscan is a global leader in the development of microscopic imaging for medical devices.

Optiscan's unique and patented technologies enable high-powered microscopes to be miniaturised and used inside the body. The technology enables microscopic imaging of up to

1000 times magnification to be achieved. Doctors can use the technology to instantly see cellular level details of tissue without the requirement to surgically remove tissue (biopsy).

Pentax is the second largest producer of flexible endoscopes in the US\$850Mpa global flexible endoscope market.

Gastroenterologists use flexible endoscopes to view inside the gastro intestinal tract. They are an essential piece of equipment in the screening, early diagnosis and treatment of colon, large intestine, stomach and oesophageal cancers and pre-cancers.

Pentax has partnered with Optiscan to license its patented miniaturised microscope technology and develop the world's first fully functional flexible endo-microscope.

Pentax's flexible endo-microscope combines existing industry standard endoscope functionality and Optiscan's unique microscopic imaging technology into one instrument. Doctors have two screens, one with the regular view (approximating 10 times magnification) and one showing the microscopic detail from Optiscan's technology (1000 times magnification).

Further information:

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