



30 April 2008

EUROPEAN MULTI-CENTRE TRIAL OF OPTISCAN'S ENDOMICROSCOPE COMMENCES

The European multi-centre trial of the Optiscan endomicroscope has commenced.

The trial, supported by Pentax Europe, began this month and will draw 200 cases from hospitals in Germany, Italy and England. It is scheduled for completion in early 2009.

The trial is focussed on Ulcerative Colitis and is similar in protocol to the single centre trial conducted at Mainz, Germany and published in the medical journal *Gastroenterology* in 2007. The major difference for the present trial is its multi-centre design. The study involves 5 hospitals, in 3 countries, each operating under the same tightly controlled protocol. The gold standard trial design allows robust measurement of both diagnostic yield and a measure of the consistency with which the technique can be replicated in different hospitals by different doctors.

The endomicroscope is currently being used in over 40 hospitals around the world.

"It's great news that the European trial has commenced. It is a key milestone along our critical path." said Optiscan CEO, Vicki Tutungi, "We are also keen to start the US multi-centre trial. We have positive trial results from single centre US studies and a number of hospitals in the US are now using the technology. Progress is being made and we are hopeful that the trial will commence in the near term."

In keeping with world health organisation guidelines, the trial has been registered with an appropriate trial registry. Details can be found at www.clinicaltrials.gov (trial identifier reference NCT00659867).

Background

Optiscan is a global leader in microscopic imaging technologies for medical markets. 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).

Optiscan manufactures and sells to Pentax the high value key operating components of the miniaturised endomicroscope system.

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