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Shareholder Update – June 2012

Confocal endomicroscopy was first brought to market by Pentax in 2006 with the Pentax ISC-1000, incorporating Optiscan's pioneering miniaturised microscopy technology. Introduction of such an innovative and disruptive technology is an expensive, drawn out and difficult process yet highly lucrative when successful. After six years in market with key opinion leaders, hundreds of publications and many thousands of procedures, numerous significant tangible factors are now supporting the mainstream take up of confocal endomicroscopy in gastrointestinal endoscopy, specifically Optiscan's technology.

Multi Centre Trial Completion

This year's Digestive Diseases Week (San Diego 19-22 May) saw the presentation of probably the most significant clinical paper on confocal endomicroscopy to date. That paper presented the findings of an International Multi Centre Randomised Controlled Trial to compare the diagnostic yield, performance characteristics and clinical impact of High Resolution Endoscopy (HRE) with endoscope-based Confocal Laser Endomicroscopy (eCLE) followed by targeted biopsy (TB) with HRE alone with TB and random biopsy (RB) for detection of Barrett's Esophagus (BE) neoplasia, the latter methodology being current best practice.

The results of the trial are quite remarkable and lead to the compelling conclusion that:

"Compared to HRE with RB, HRE with eCLE and TB improved detection of BE neoplasia with significantly fewer biopsies. eCLE led to greater sensitivity for diagnosis of neoplasia compared to HRE alone and impacts decision making."

The major specific data leading to that conclusion being:

- 178 of 200 enrolled patients were evaluated at the time of analysis.
- On a per biopsy analysis, the overall diagnostic yield for neoplasia was 5.2 fold greater using eCLE (45.6% vs 8.8%), despite fewer biopsies being obtained.
- Despite fewer biopsies, 100% sensitivity was achieved (no missed disease).
- On a per patient analysis, HRE with eCLE led to a 4 fold increase in diagnostic yield for BE neoplasia.
- In 26 Group B (HRE with eCLE) lesions, eCLE changed the HRE diagnosis to a correct diagnosis in 15 (53.6%) and correctly changed the treatment plan in 9 (34.6%).

This data underpins a "diagnose and treat" process that delivers significant patient, clinician and health care system benefits.

Optiscan is delighted with the conclusions reached by this trial using its technology (eCLE) that was undertaken at 5 prestigious institutions, being:

- Johns Hopkins Medical Institutions, Baltimore, MD
- Mount Sinai School of Medicine, NY, NY
- Massachusetts General Hospital, Boston, MA
- University of Pennsylvania, Philadelphia, PA
- University of Mainz, Mainz, Germany



Barrett's Esophagus

While the conclusions of the multi centre trial are significant, so is the market specific to Barrett's Esophagus (BE) in the multi-billion dollar gastrointestinal endoscopy market.

In a study published in 2005, BE was estimated to affect approximately3.3 million adults in the US alone. BE can lead to esophogeal adenocarcinoma, a dangerous cancer with a five year survival rate of around17%. BE progresses to high grade dysplasia or cancer at a combined rate of 1.4% per patient per year, with 0.5% per year developing cancer. Esophogeal adenocarcinoma is now the fastest growing form of cancer in the US, growing from an already significant level. Its incidence is rising faster than breast cancer, prostate cancer and melanoma and in part highlights the need for better solutions – "diagnose and treat".

Optiscan Technology Dominant

To add further weight to the Level 1 evidence from the trial that eCLE plus HRE is the dominant technology, is the recent approval of three category 1 CPT codes regarding the use of optical endomicroscopy in the GI tract, with those codes scheduled for implementation in January 2013. CPT codes are the most widely accepted nomenclature used to report medical procedures and services under US private and public health insurance programs, and are a prerequisite for obtaining coverage from health insurers (often referred to as 'reimbursement'). This represents a significant milestone in the path to widespread adoption of a new technology.

There are many other applications for eCLE in the gastroenterology (GI) tract, at this point BE is the most advanced and one of the largest markets.

Of note the results of another multi centre trial were also recently presented at DDW. That trial presented the results of a pCLE (Mauna Kea Technology) trial and concluded:

"no evidence that the addition of pCLE to High Definition White Light imaging for detection of residual BE or dysplasia can provide improved treatment."

Further evidence that Optiscan's technology is gaining real traction in GI is the recent receipt of its first relevant royalty payment (Generation 1) over the Pentax ISC-1000.

These factors provide an enviable platform to enable Optiscan's successful entry to the GI endoscopy market with its second generation technology, with the commercial path to re-entry expected to be finalised within months.

Neurosurgery and ENT

Optiscan is well advanced with the development of a number of pre-production prototypes of its rigid endomicroscopy system for neurosurgery to be exclusively supplied to Carl Zeiss, the world's number one supplier of neurosurgical visualisation equipment. These units will facilitate the final steps in the safety and effectiveness testing of the device as a precursor to achieving regulatory clearance, and are likely to be deployed within months. In addition to neurosurgery, some very promising studies have been and continue to be undertaken in ENT, where Optiscan will also supply systems exclusively to Carl Zeiss.



Summary

Optiscan is entering a very exciting phase of its evolution with access to multiple global markets with leading-edge technology. There is also a long list of attractive applications that have not yet been fully investigated with the same depth as GI and neurosurgery but which show as meaningful preliminary imaging value.

Beyond our immediate focus of bedding down market access and penetration for our leading second generation technology, Optiscan's philosophy of delivering the highest quality cellular images is paramount for ongoing value creation. Endomicroscopy with images of a diagnostic quality allowing the transition to telepathology at a cellular level is the logical advancement from today's significant visualisation and biopsy targeting benefits of endomicroscopy. Optiscan's image quality is on its own at this level and continues to improve.

Once again, we appreciate the support, loyalty and patience of our shareholders and look forward to more exciting developments soon.

About Optiscan

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).

Further information:

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