Media Release

Straumann launches Roxolid™ in Europe and presents clinical update at EAO

- *New material combines higher tensile and fatigue strengths[1] with excellent osseointegration[2] and is designed to increase reliability and confidence with small diameter implants*
- *Results of double-blind, randomized, controlled, clinical study show minimal crestal bone level change after one year[3]*
- *More than 7000 Roxolid implants in controlled release program*
- *Less invasive treatment using smaller implants is expected to increase patient acceptance of implant solutions*

Basel 5 October 2009: At the 18th Annual Meeting of the European Association for Osseointegration (EAO) in Monaco, Straumann announced the European launch of its new high performance dental implant material Roxolid™. As a result, Roxolid Ø3.3mm Bone and Soft Tissue Level implants are now available in Europe and throughout North America, where the new material was launched two weeks ago. Straumann also made use of the EAO to provide an update on two large multicenter clinical trials that are currently in progress.

Update on company's largest prelaunch clinical program to date
Roxolid has been undergoing a broad program of clinical trials in 9 countries, the first of which began more than 2 years ago. Involving 60 centers and more than 300 patients, this is one of the largest clinical research programs ever undertaken by a dental implant company prior to market launch. Initial preclinical and clinical reports have already been presented by lead investigators at recent major congresses[2,4,5,6,7].

At the EAO, Prof. Bilal Al-Nawas, Medical Director at the Department of Oral, Maxillofacial, and Plastic Surgery at the J. Gutenberg University of Mainz in Germany, presented a review of the scientific evidence including an update on two major clinical trials on Roxolid.

The first, in which Prof. Al-Nawas is the principal investigator, is a double-blind randomized controlled clinical trial (RCCT), which has been running in 8 European centers for more than a year. Ninety-one edentulous patients have each been treated with one control implant (titanium SLActive) and one test implant (Roxolid SLActive), which together carry a removable denture. After one year, 89 patients with 178 implants were analyzed. Only 3 implants were lost (2 in the titanium SLActive group and 1 in the Roxolid SLActive group). Importantly, the evaluation showed that there were minimal changes in crestal bone level after one year (0.31mm with titanium SLActive and 0.34 mm for Roxolid SLActive). The difference was not statistically significant.

RCCTs provide the highest level of clinical evidence and Straumann believes that this is the first double-blind RCCT of this scale to investigate a new dental implant material

prior to market launch. Furthermore, it is very rare in implant dentistry for a company to compare a new product head to head with an existing gold standard in an independent multicenter setting.

The study therefore sets a benchmark and will continue to assess various parameters over 2 and 3 years, including soft tissue and bone maintenance, as well as implant survival and prosthetic success.

The other trial discussed is a non-interventional clinical study (NIS) running in more than 50 centers in Europe and North America. With the goal of assessing the performance of Roxolid in daily clinical practice, over 400 implants have now been placed in 235 patients, more than 60% of whom been tracked for more than 6 months.

In more than 50% of the cases treated in the NIS, dentists said that bone augmentation would have been needed if an implant wider than 3.3mm had been used. To date, only two implant losses have been reported (both were immediate placements in extraction sockets). The very low reported failure rate is remarkable in view of the fact that this study is being carried out under ordinary daily practice conditions and includes patients with risk factors.

Apart from the clinical program, Roxolid was made available to 450 selected specialists in a controlled release program, in which more than 7000 implants were distributed.

Straumann also announced today that its clinical program has been extended to include studies looking specifically at the need for bone augmentation and at the performance of Roxolid in the front of the mouth and in narrow spaces. The preclinical program has also been broadened to investigate healing characteristics and to draw direct comparisons with other titanium alloys.

About Roxolid
Roxolid™ is an alloy of titanium and zirconium that combines high tensile and fatigue strengths[1] with excellent osseointegration[Error! Bookmark not defined.] and is designed to increase reliability and confidence with small diameter implants.

Rigorous tests in Straumann laboratories have shown that it has higher fatigue and tensile strength than pure titanium (grade 4 annealed and cold worked)[1,3], the current material of choice for dental implants. In addition, preclinical study results have indicated that bone integrated with Roxolid better than with pure titanium (grade 4)[8].

The need for high performance materials
Pure titanium is well known for its biological compatibility with the human body, its resistance to corrosion, and its strength. However, its mechanical properties are limited in the case of small diameter implants or parts, which are needed for narrow spaces. This prompted the use of alternative materials, such as titanium alloys (e.g. Ti-6Al-4V, 'TAV'), but additional strength came at the price of impaired osseointegration due to inferior biocompatibility and surface characteristics[9,10,11,12].

According to published research[9], titanium and zirconium are the only two metals commonly used in implantology that do not inhibit the growth of osteoblasts, the bone forming cells that are essential for osseointegration. In contrast, the alloy of titanium and vanadium (TAV) has been shown to compromise osseointegration[11,12].

Furthermore, TAV cannot accommodate the sophisticated microstructuring processes required for Straumann's third generation SLActive® surface technology, which enhances osseointegration.

The potential of smaller implants

In the future, high strength, small diameter implants with enhanced osseointegration properties are expected to offer a number of advantages to dental professionals and patients, including: enhanced esthetics, broader treatment options, shorter treatment times and reduced costs. This is important as patients often fear implant treatment because of the associated pain, duration and cost. Straumann believes that Roxolid will therefore increase the general acceptance of implant dentistry and will contribute to further enhancing confidence among practitioners placing implants.

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About Straumann

Headquartered in Basel, Switzerland, the Straumann Group (SIX: STMN) is a global leader in implant and restorative dentistry and oral tissue regeneration. In collaboration with leading clinics, research institutes and universities, Straumann researches, develops and manufactures dental implants, instruments, prosthetics and tissue regeneration products for use in tooth replacement and restoration solutions or to prevent tooth loss. Straumann currently employs approximately 2200 people worldwide and its products and services are available in more than 70 countries through its broad network of distribution subsidiaries and partners.

Photographs and further information

Photographs for journalistic use together with further information are available at http://straumann.imagedirector.net/albums?album_code=ph3ej3z5w54n.

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