

Boston Sci inks plea deal

Guidant criminally charged with concealing information from FDA

By LYNN YOFFEE

Medical Device Daily Staff Writer

The price that **Boston Scientific** (Natick, Massachusetts) has paid for troubled cardiac rhythm management firm **Guidant** has far exceeded its 2006 winning bid of \$27.2 billion. Plagued with product liability problems, Guidant has cost Boston Sci millions more to settle lawsuits related to electrical flaws in its implantable cardioverter defibrillators (ICDs). And now those troubles have led to alleged criminal violations of the Federal Food, Drug, and Cosmetic Act. Charges were filed yesterday by the Department of Justice (DOJ) in federal district court in St. Paul, Minnesota.

Late Thursday, a Boston Scientific spokesman told *Medical Device Daily* that the company has already signed a plea agreement with the DOJ.

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US HIFU to fund trial of focal therapy for prostate cancer

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

All too often when a man is diagnosed with prostate cancer he falls into a sort of gray area. Because of the side effects associated with surgery or radiation treatment (usually incontinence and impotence), he may be encouraged to take the "wait and see" – or, active surveillance – approach. Yet the idea of doing nothing is a bit unsettling as well.

US HIFU (Charlotte, North Carolina), a developer of minimally invasive high intensity focused ultrasound (HIFU) technologies, is hoping to offer men with early-stage, low-risk prostate cancer a happy medium solution to this dilemma.

The company says it intends to fund a landmark multi-center trial to study focal therapy for localized prostate cancer. Mark Emberton, MD, consultant urological surgeon

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Washington roundup

AdvaMed commissions study of comparative med-tech innovation

By MARK McCARTY

Medical Device Daily Washington Editor

WASHINGTON – The device and diagnostics industries are knee-deep in a number of issues, and the **Advanced Medical Technology Association** (AdvaMed; Washington) promises it will be in the mix again this year. One widely anticipated change at AdvaMed is the turnover at the position of chairman of the board, soon to be vacated by Michael Mussallem, CEO of **Edwards Lifesciences** (Irvine, California), whose replacement will be Jim Mazzo, president/CEO of **Abbott Medical Optics** (Santa Ana, California).

Mussallem and Steve Ubl, AdvaMed's president/CEO, offered no bombshells at their annual policy briefing Wednesday, but they did announce that the association is taking square aim at the device lag issue by commission-

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Deals roundup

Teleflex in pact to acquire SSI Surgical Services for \$25 million

A *Medical Device Daily Staff Report*

Teleflex (Limerick, Pennsylvania) said that it has entered into a definitive agreement to sell its **SSI Surgical Services** (Orlando, Florida) business to a privately-owned multi-service line healthcare company for nearly \$25 million. The transaction is subject to customary closing conditions and is expected to close before the end of 1Q10.

"The decision to divest SSI was made following a review of our portfolio and it was determined that SSI was not a strategic fit. This allows us to continue to reallocate resources to our higher margin businesses," the company said.

SSI, with annual revenues of nearly \$20 million, offers a range of endoscopic surgical services and sterile processing management services to help hospitals and surgery centers control costs and improve operational efficiency.

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HIFU

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and divisional clinical director of cancer services at **University College London Hospital** (UCLH), along with Hashim Uddin Ahmed, MRC clinical research fellow, will lead the trial.

When a patient is in that gray zone – too nervous to just sit and wait, but also not wanting to risk the side effects of radical intervention – “either whole gland HIFU or focal therapy, to an increasing degree, is going to be that balancing act,” US HIFU CEO Steve Puckett, Jr., told *Medical Device Daily*. Speaking from the third International Symposium on Focal Therapy and Imaging of Prostate and Kidney Cancer in Washington, Puckett said focal therapy for localized prostate cancer offers men an option that bridges the gap, so that “it’s not just one end or the other of the spectrum.”

The primary objectives of the trial are to evaluate quality of life outcomes and safety of focal therapy in the treatment of localized prostate cancer, US HIFU said. A secondary objective is to measure the costs of treatment and model the cost-effectiveness of focal therapy using the company’s Sonablate 500 technology. The study will involve four centers initially and may expand to as many as 10 centers in the U.K., the company noted. Puckett said the study should start enrolling patients in about a month.

“I believe that focal treatment is the future for early-stage, low-risk cancer. Considering the treatments that are currently approved and available worldwide, men with localized prostate cancer may often feel they must choose between active surveillance and radical therapy (surgery or radiation),” Emberton said. “Patients who opt to monitor their cancer run the risk of having the disease spread, while those who choose radical therapy are at increased risk for incontinence and impotence. I see focal therapy as a cost-effective solution that can potentially provide an optimal balance between cancer control and co-morbidity issues.”

The ability to accurately and precisely detect cancerous lesions as well as ongoing disease monitoring, and management if necessary, are keys to effective focal therapy and paramount to trial designers, US HIFU noted.

“Over the past year, US HIFU has been working with thought leaders around the world to come up with what we believe is the most well thought-out and defensible trial design to initially evaluate HIFU-induced focal therapy while compensating as thoroughly as possible for the flaws associated with biopsy diagnosis,” Puckett said.

He told *MDD* that there is “broad confusion in the United States” about how to deal with focal therapy in the prostate from a regulatory perspective. “What are the appropriate endpoints for focal design where you’re not ablating the entire prostate, so clearly there’s going to be continuous PSA (prostate-specific antigen) where a whole gland ablation trial you can look toward the complete elimination of PSA as an endpoint.”

Puckett said US HIFU will perform the trial in the UK not

as a registration study, but more as an academic study that the company believes all other focal therapy studies in the future will be measured against.

He added that whole gland HIFU is already in use in international jurisdictions where it is approved and is showing efficacy in that it consistently results in a reduction in morbidity in terms of incontinence and impotence.

“That is why we are so excited about not only focal, but then the whole gland as well because it is showing internationally to reduce incontinence and impotence” in addition to not requiring a hospital stay and allowing most patients to return to work the next day, Puckett said.

Focal ablation could take the benefits of whole gland HIFU to a whole new level.

“Not only does HIFU as a category take it from a hospital stay to outpatient procedure, focal takes the procedure from three hours for whole gland ablation down to somewhere between 15 and 45 minutes,” Puckett said. “So, far less theatre time and then there’s much less catheterization time post-procedure, if at all, because there’s not nearly as much tissue that needs to be fluffed out after ablation.”

That is why the company is looking at cost-effectiveness of the therapy as a secondary objective of the study. Puckett said focal therapy reduces the use of anesthesia supply as well as the anesthesiologist’s time and the urologist’s time, plus occupancy in the facility.

According to the company the Sonablate HIFU for prostate cancer is a minimally invasive, targeted approach to treating disease with precision-focused ultrasound energy that, when delivered, raises the temperature of the tissue in a matter of seconds. The extreme, rapid-firing heat destroys the tissue at a specific target, known as a lesion, which measures 12x3x3 mm, roughly the size of a grain of rice. Lesions are created throughout the prostate that result in its destruction, US HIFU said.

The Sonablate 500 is not approved for use in the U.S., however, the device is being studied for the treatment of prostate cancer in U.S. clinical trials, the company noted.

“The management of prostate cancer is entering a time of dramatic change,” said Naren Sanghvi, US HIFU’s chief scientific officer. “While surgery and radiation therapy will continue to play important roles in the treatment of some patients, new approaches designed to serve those with minimal, focal or slow-growing cancer, for example, deserve scholarly attention and merit evaluation in bona fide clinical trials. The Emberton Study, supported by US HIFU, attempts to address issues central to an emerging new paradigm in cancer management, which could be termed ‘therapeutic surveillance.’ The goal of therapeutic surveillance would be focal, possibly repetitive, cancer ablation with minimal morbidity facilitated by serial non-invasive imaging.” ■

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