



Bactiguard's technology receives regulatory clearance in China

At an expert panel session on 4 June 2014, the Chinese Center for Medical Device Evaluation (CMDE) informed that it will approve Bactiguard's BIP Foley catheters. This is a major step en route towards final regulatory approval and commencement of sales in mainland China.

The most important step in achieving regulatory approval for Bactiguard's BIP Foley catheters on the Chinese market has now been achieved. CMDE yesterday informed that it will approve BIP Foley catheters. CMDE is the division within the China Food and Drug Administration (CFDA) responsible for technical and clinical review, which includes product testing and expert review. Upon receipt of the dossiers from CMDE, CFDA will pursue an administrative examination of the manufacturing file and decide on final product approval.

"This approval is a major milestone for Bactiguard and has the potential to open up one of the largest and fastest growing markets in the world. The Chinese Foley market is estimated to 50-70 million units annually. The decision by CMDE means that Bactiguard's technology has received regulatory clearance in China. This also paves the way for Bactiguard's coming product approval applications for endotracheal tubes (BIP ETT) and central venous catheters (BIP CVC). From a value perspective these products have an even greater potential than the Foley catheters," says Bactiguard's CEO Johan Rugfelt.

In 2011, Bactiguard signed a distribution agreement with Jian An Pharmaceutical, which has more than 2 000 sales representatives and 5 000 hospitals as their customers in China.

"Bactiguard has a unique and clinically proven solution in preventing healthcare associated infections and we believe it has great potential on the Chinese market," says Jian An's CEO, Zhangyi Zhan.

"Jian An has the ambition to achieve a remarkable share of the Chinese Foley market within the coming few years. Hence, we are looking forward to receiving the final regulatory approval and we have started planning for commencement of sales to Chinese hospitals. With the CMDE clearance, Bactiguard has – during the past 12 months - received green light in the major BRIC countries India, Brazil and China. Therefore, we are now very well positioned to execute on our expansion plans." Johan Rugfelt concludes.

Healthcare associated infections (HAI) are a global problem and the third largest cause of death in the western world. In China, the numbers are also significant. Urinary tract infections account for close to one third of HAI in the western world. Bactiguard's technology has been tested in 37 clinical studies in eight countries, on more than 100 000 patients. On average, a 39 percent reduction in catheter related infections has been proven, and up to 60 percent in several major clinical studies. Moreover, more than 130 million patients have been treated with Bactiguard-coated products, with no reported negative side effects.

Bactiguard Holding AB (publ) is required to disclose the above information under the provisions of the Securities Market Act and/or the Swedish Financial Instruments Trading Act. The information was submitted for publication at 8:35 AM CET on 5 June 2014.

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Bactiguard

Bactiguard is a Swedish medtech company with a business concept of preventing healthcare associated infections, reducing the use of antibiotics and saving lives by developing and supplying infection prevention solutions for the healthcare industry. The company's patented coating prevents healthcare associated infections by reducing bacterial adhesion and growth on medical devices. Bactiguard®-coated urinary catheters are market leading in the US and Japan, and in recent years the company has developed its own product portfolio of coated catheters for the urinary and respiratory tract and the blood stream. Bactiguard is currently in a strong expansion phase, focused on new markets in the EU, Middle East, Asia and South America. The company reported sales of approximately SEK 130 million in 2013, has 60 employees, headquarters in Stockholm and production facilities in Markaryd and Malaysia.