Press release **Stockholm 5 December, 2018**

CE-mark opens the door to billion-dollar market for orthopaedic trauma implants

Orthopaedic trauma implants in titanium with Bactiguard's coating for infection prevention have been CE marked and can, from now on, be sold and used in markets that apply EU quality standards. At the same time, the CE-mark opens possibilities for Bactiguard to establish new license agreements covering more markets. The global market for trauma implants is estimated at over 5 billion USD[1].

"The CE mark we have now secured is a major breakthrough for Bactiguard. It is the first time our technology has been approved for use on metal implants, designed to stay in the body for months up to several years. At the same time, it opens the door to the global market for trauma implants, with an annual turnover of more than 5 billion USD. We will therefore focus on establishing new partnerships within this application area, primarily for the EU and the US markets," said CEO Christian Kinch.

"Infections are common and extensive among patients who suffer from severe fractures, often caused by accidents. This leads to complications, sometimes with amputation as a last resort. By reducing the risk of infections, we can significantly improve patient safety and quality of life for those who suffer from these conditions and that makes us proud," Christian Kinch continues.

In late 2015, Bactiguard and Vigilenz Medical Devices (Vigilenz), a Malaysian manufacturer and supplier of medical disposables and surgical products, signed a license agreement for Bactiguard coated orthopaedic trauma implants. The agreement includes the right to market and sell these implants in the South East Asian ASEAN region. Bactiguard's aim was to expand its licensing business to new therapeutic areas and Vigilenz's ambition was to strengthen its existing product range by enhancing it with infection preventive properties.

Clinical studies were initiated in parallel with the regulatory process and interim data show good results. Data from the first patients included in the study have also served as input to the CE mark. The trauma implants have been classified as Class IIb, i.e. the same risk class as the underlying devices (without Bactiguard coating).

With the new CE mark as a precedent, Bactiguard intends to establish new partnerships and enter new agreements with one or more major trauma implant manufacturers covering the rest of the world.

The global market for trauma implants is estimated to exceed USD 5 billion, which is almost three times the global market for all products currently included in Bactiguard's own portfolio

[1] Source: Global Data 2018

for infection prevention (indwelling urinary catheters, central venous catheters and endotracheal tubes).

This information is information that Bactiguard Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below 2018-12-05, at 08:00

For further information, please contact:
Cecilia Edström, CFO, cell phone: +46 72 226 23 28

About Bactiguard
Bactiguard is a Swedish medical device company with a mission to save lives. To achieve this mission, we develop and supply infection prevention solutions which reduce the risk of healthcare associated infections and the use of antibiotics. This way, we save significant costs for healthcare and the society at large.

The Bactiguard technology prevents bacterial adhesion and biofilm formation on medical devices. Bactiguard offers the technology through licence agreements and our BIP (Bactiguard Infection Protection) portfolio of products. Through our licence partner BD, urinary catheters with Bactiguard's coating are market leading in the USA and Japan. Bactiguard's own product portfolio of urinary catheters, endotracheal tubes and central venous catheters prevent some of the most common infections, which appear in the urinary tract, the blood stream and the respiratory tract.

Bactiguard is in a strong expansion phase in the European markets, China, India and the Middle East as well by establishing license agreements in new therapeutic areas. The company has about 70 employees around the world. Its headquarters and one of two production facilities are in Stockholm, the other one in Malaysia. Bactiguard is listed on Nasdaq Stockholm.

Read more about how Bactiguard saves lives at www.bactiguard.com