

Press release

Stockholm, 21 January 2021

Bactiguard-coated Zimmer Biomet trauma implants receive European regulatory clearance

Today, Bactiguard-coated Zimmer Biomet orthopaedic trauma implants received European regulatory clearance and CE mark. Preparations for registering the implants in the U.S. market are also ongoing.

"I am very pleased that the CE mark has been secured for Bactiguard-coated Zimmer Biomet trauma implants. This clearance will pave the way for European market launch in 2021. At the same time, we are preparing for the submission of the U.S regulatory file", says Cecilia Edström, Bactiguard CEO.

The partnership with Zimmer Biomet has the potential to expand Bactiguard's current license business and make a substantial contribution to its recurring license revenues.

Background to Bactiguard's license agreement with Zimmer Biomet

In 2015, a partnership was initiated between Bactiguard and Vigilenz Medical Devices for Bactiguard coated orthopaedic trauma implants, covering the ASEAN region in South East Asia. The implants were CE marked in December 2018 and have been used as a reference in the process of obtaining regulatory clearance for Zimmer Biomet's trauma implants. Vigilenz Medical Devices was acquired by Bactiguard in 2020 and is now a wholly-owned subsidiary.

In September 2019, Bactiguard entered an exclusive, global license agreement for orthopaedic trauma implants with Zimmer Biomet. The agreement included an upfront license fee of USD 3 million, additional contingent payments of USD 2 million based on U.S. regulatory clearance and royalties on net sales following commercialization.

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 2021-01-21, at 18.30.

For further information, please contact:

Cecilia Edström, CEO, phone: +46 72 226 23 28





Trauma implant

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 infections and the use of antibiotics. This way, we save significant costs for healthcare and the society at large.

The Bactiguard technology is based on a thin noble metal alloy coating that 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 product portfolio also includes Hydrocyn® aqua, a non-alcoholic and pH-neutral product line that contains hypochlorous acid, the same substance as the body's immune cells use in their defense against infectious organisms. Hydrocyn effectively kills viruses, bacteria and fungi without causing irritation to the skin or body.

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.

Bactiguard has about 180 employees around the world. Its headquarters and one of three production facilities are located in Stockholm, the other two in Malaysia.

Bactiguard is listed on Nasdaq Stockholm.

Read more about Bactiguard www.bactiguard.com