

Press Release – Final

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In-Vivo Study with Biofilm Resistant Silicone Implants Presented at BTS

- *Animal study to be presented at BTS reports strong anti-biofilm properties of implants with Nobio's technology, in light of concerns for cancer linked to breast implants -*

KADIMA, ISRAEL (June 7, 2019) – Nobio Ltd., developer of embedded, long-acting antimicrobial particle technology, today announced results of first in-vivo study in silicone implants incorporating its anti-biofilm technology. Nobio developed a silicone-application of its anti-biofilm embedded technology to address the recently increasing concerns for complications linked to biofilm growth on breast implants, primarily breast-implants associated anaplastic large cell lymphoma (BIA-ALCL), a rare type of cancer, and more commonly capsular contracture, which may cause visible deformities of the breast.

The study evaluated the in-vivo anti-biofilm protective effect of Nobio's technology, when incorporated into medical-grade silicone implant, compared to implant of the same silicone material without Nobio's technology. In this self-controlled animal study on mice, a pair of implants (with and without the Nobio technology) were inserted into the back of each individual mouse in two separate subdermal pockets. Prior to implantation, the silicone samples were contaminated with high concentrations of either *Staphylococcus aureus* or *Enterococcus faecalis* bacterial species. The tested samples were explanted after a period of between 1 to 12 weeks and assessed for biofilm using microbiology assays (CFUs counts), scanning electron microscopy (SEM) and histology. Microbiological studies have shown that the silicone samples containing Nobio nanoparticles had a strong anti-biofilm effect in vivo at all examined time points. The histopathological studies of the capsules surrounding the implants containing Nobio particles showed a thinner fibrous capsule with few inflammatory cells while the capsules surrounding of the silicone samples, without the Nobio technology, showed thick fibrous capsule, which was rich with inflammatory cells. Some animals developed acute inflammation and abscess around or near the control implant, but no inflammation or other clinical signs were seen around the Nobio implant.

The study was presented by Dr. Eitam Weiss, plastic surgeon and one of the study investigators, at the upcoming annual Beauty through Science (BTS) meeting, taking place in Stockholm, Jun 5-8, 2019.

“Increasing number of cases of BIA-ALCL is driving regulators and industry to focus and take actions regarding this highlighted concern for patient safety,” said Dr. E. Weiss. “Biofilm on breast implants may have a strong role in the formation of BIA-ALCL, however, it is proven to be a key contributor to capsular contracture and infections, therefore biofilm resistant breast implants are an important development and potential game-changing technology in this field.”

Breast Implant Associated Lymphoma (BIA-ALCL) is a rare type of non-Hodgkin’s lymphoma (cancer of the immune system), found in most cases in the scar tissue (capsule) and fluid around the implant. Although, the risk of developing BIA-ALCL is considered to be very low, in some cases this form of cancer can lead to death, especially if not treated promptly or undiagnosed. The vast majority of reported cases involve the usage of a rough texture surface silicon shell, which is now banned and removed from certain markets.

About Nobio

Nobio Ltd. is an advanced materials science company offering novel antimicrobial products and solutions. The health and economic burden of bacteria is enormous, and in three decades, resistant bacteria may kill more people than all cancers combined. Bacteria cause infections mostly by colonizing and forming biofilms on surfaces of almost any product or solid material. Nobio’s breakthrough particle-based technology transforms common materials to antimicrobial, keeping them free of bacterial colonization and biofilm, indefinitely. Nobio is now focused on dental applications, where bacteria are the leading cause for failure of most treatments, and medical devices, which are linked with most healthcare associated infections, one of the 10 top causes of deaths in developed countries. For more information, visit www.nobio.com.

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