

SOFTOX GETS APPROVAL FOR FIRST CLINICAL STUDY IN ACUTE WOUNDS

Oslo, 31. October 2018

SoftOx Solutions AS (SoftOx) has received approval from the Danish Medicines Agency and Ethics Committee to conduct the Company's first-in-man clinical trial with its wound cleansing product, abbreviated SWIS. The study aims to establish safety and performance properties of SWIS in preventing bacterial colonisation and infection in patients with acute wounds.

Rapid Approval

The Company submitted a clinical trial application for its first medical device product to the regulatory authorities in Denmark in August this year. *"The preparation for clinical studies has been done in record time"*, says Geir Almås, CEO of SoftOx. "The study will start 9th November and will according to protocol be finalised before mid-April next year."

Major Milestone

"The approval by the Regulatory Authorities in Denmark is a major milestone for SoftOx and proves the quality of the documentation and medical relevance of our first medical device product", says Medical Director, Glenn Gundersen. The study will be performed at Bispebjerg University Hospital in Copenhagen, Denmark.

Highly effective in killing bacteria and other microorganisms

The development of SoftOx' proprietary technology platform and product leads have been done in cooperation with The University of Copenhagen, more specifically The Costerton Biofilm Center and Rigshospitalet. The basis for this technology is a combination of natural chemical agents that is well known to the human body, thus making them well tolerated in use while at the same time being highly effective in killing bacteria and other microorganisms – without inducing resistance. Laboratory experiments have shown outstanding microbicidal effects – both on free-floating (planktonic) and biofilm embedded microbes, including pathogens on WHO's (World Health Organisation) list of bacteria resistant to antibiotics.

Contribute to solve the increasing healthcare challenge of antibiotic resistance

"It is impressive that SoftOx has completed its preclinical study program during first half of 2018. The results give us reason to be very optimistic and that our collaboration with SoftOx may contribute to solve the increasing healthcare challenge of antibiotic resistance and biofilm infections in chronic wounds", says Thomas Bjarnsholt, Professor at Costerton Biofilm Center, University of Copenhagen."

"Our close and excellent cooperation with the world leading scientific team at University of Copenhagen has been a precondition for achieving these results", says Almås.

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About SoftOx:

SoftOx Solutions AS (SoftOx) is a Norwegian MedTech company established in 2012 and listed on Merkur, Oslo Stock Exchange (SOFTOX-ME). The Company's proprietary technology is focused on developing antimicrobial products that do not contain classical antibiotics or induce microbial resistance, aiming to prevent and treat biofilm-associated infections, either as medical device or pharmaceutical products. SWIS, a medical device class III, is the Company's first product reaching clinical phase. For more information about SoftOx, see www.soft-ox.com, or contact Geir Almås: e-post: geir.almaas@soft-ox.com, mobile: +47 977 59 071.