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Ondine Biomedical Inc.
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ONDINE BIOMEDICAL INC.

("Ondine Biomedical", "Ondine", or the "Company")

Ondine recruits first patient for US Phase 3 trial

Ondine Biomedical Inc. (LON: OBI), a Canadian life sciences company, has enrolled and treated the first patient in the Light-Activated Antimicrobial Therapy to Prevent Surgical Site Infections ('LANTERN') Phase 3 clinical trial. The trial, involving approximately 5,000 patients in 14 hospitals, is evaluating Ondine's non-antibiotic nasal photodisinfection technology, branded as Steriwave® outside the US. The first patient was enrolled at Centennial Medical Center in Nashville, Tennessee, on Friday December 27th, 2024.

The Phase 3 trial is being conducted in collaboration with HCA Healthcare, a leading healthcare provider in the United States. This group-randomized crossover study will enroll approximately 5,000 surgical patients undergoing cardiac, orthopaedic, vascular, neurosurgical or radical mastectomy procedures. The study will compare standard infection prevention practices with, and without, Ondine's nasal photodisinfection technology in order to reduce the incidence of surgical site infections. The final patient is expected to enroll in mid-2025, and preliminary trial results are projected for release in Autumn 2025.

Ondine Biomedical's CEO Carolyn Cross said:

"Our US Phase 3 trial initiation is an exciting milestone towards making photodisinfection technology available to healthcare professionals who want to rapidly eliminate a broad spectrum of infection-causing pathogens without fuelling drug resistance or relying on patient compliance as is the case with topical antibiotics."

Ondine's nasal photodisinfection is a 5-minute, non-invasive procedure that rapidly decolonizes the nose of infection-causing pathogens without the use of antibiotics. This innovative approach avoids contributing to antimicrobial resistance (AMR). The process involves applying a proprietary photosensitive agent to each nostril with a nasal swab, followed by illumination with a specific wavelength of red light. The light activates the agent, producing an oxidative burst that destroys bacteria, viruses and fungi in a single treatment.

Nasal decolonization is recommended in the 2016 WHO Global guidelines for the prevention of surgical site infections,[1] and the Society for Healthcare Epidemiology of America (SHEA) guidelines, published in May 2023, recommend nasal decolonization for major surgical procedures.[2]

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About Ondine Biomedical Inc.

Ondine Biomedical Inc. is a Canadian life sciences company and leader in light-activated antimicrobial therapies (also known as 'photodisinfection'). Ondine has a pipeline of investigational products, based on its proprietary photodisinfection technology, in various stages of development.

Ondine's nasal photodisinfection system has a CE mark in Europe and is approved in Canada and several other countries under the name Steriwave®. In the US, it has been granted Qualified Infectious Disease Product designation and Fast Track status by the FDA and is currently undergoing clinical trials for regulatory approval. Products beyond nasal photodisinfection include therapies for a variety of medical indications such as chronic sinusitis, ventilator-associated pneumonia, burns and other indications.

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[1] Surgical Site Infection Prevention: Key facts on decolonization of nasal carriers of Staphylococcus aureus. World Health Organization. (link)

[2] Calderwood MS, Anderson DJ, Bratzler DW, et al. Strategies to prevent surgical site infections in acute-care hospitals: 2022 Update. Infect Control Hosp Epidemiol. 2023;44(5):695-720. (link)

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