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Ondine Biomedical Inc.
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ONDINE BIOMEDICAL INC.

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

Ondine commencing US Phase 3 clinical trial

Ondine Biomedical Inc. (LON: OBI), a Canadian life sciences company pioneering light-activated antimicrobial treatments, announces the imminent start of the LANTERN Phase 3 clinical trial of its novel nasal photodisinfection technology, branded as Steriwave® outside the US. The U.S. Food and Drug Administration (FDA) has raised no objections to starting the study during its statutory 30-day review period of the Company's Investigational New Drug (IND) amendment, thereby allowing the trial to begin.

Preparations for this pivotal trial are nearly complete, with all 14 hospital sites selected and two additional back-up sites identified. Ondine has already initiated four sites and has been conducting staff training to ensure readiness for patient enrolment. Patient recruitment activities are beginning and will continue through early 2025, with the final patient expected to enrol in mid-2025. Early trial results are projected for release in Autumn 2025.

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, orthopedic, vascular, neuro or radical mastectomy surgeries. The study will compare standard infection prevention practices with and without Ondine's nasal photodisinfection technology.

CEO Carolyn Cross stated:

"The significant recent funding has been pivotal in enabling us to move forward with the launch of our US Phase 3 trial before the end of the year. This critical study marks a key milestone in our pursuit of FDA approval for our nasal photodisinfection technology. We're thrilled by the strong engagement from our clinical trial investigators and hospital research teams and are excited to commence the trial with the support of our clinical trial partner, HCA Healthcare."

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.

[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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