MolecuLight *i:X®* Receives FDA 510(k) Clearance for the Device's Ability to Detect Wounds Likely to Contain *Pseudomonas aeruginosa (PA)*

New FDA Clearance Illustrates the Utility of the ***i:X*** to Reliably Predict *Pseudomonas aeruginosa*, a Bacterial Pathogen that Precludes Wound Healing and Often Evades Conventional Treatment Methods

TORONTO, CANADA – (September 23 2021) MolecuLight Inc., the leader in point-of-care fluorescence imaging for real-time detection of wounds containing elevated bacterial loads, announces that it has received FDA 510(k) clearance for the detection of wounds containing clinically significant levels (>10^4 CFU/g) of *Pseudomonas aeruginosa (PA)* for the previously cleared MolecuLight ***i:X*** imaging device. The ***i:X*** device visualizes fluorescence, enabling the point-of-care detection of wounds containing elevated levels of bacteria. This new FDA clearance supports the ability of the ***i:X*** device to increase the clinician's ability to detect the presence of *Pseudomonas aeruginosa* in wounds using the cyan fluorescence signal. This augmented labeling is based on a detailed retrospective statistical analysis of over 350 patients.

Pseudomonas aeruginosa (PA) is a common bacterial pathogen that precludes wound healing. PA is notorious for its intrinsic resistance to many antibiotics and its tendency to form biofilm matrices that evade antibiotics and other conventional treatment methods[1]. The presence of PA in wounds is associated with rapid deterioration and more severe wound outcomes[2,3]. The MolecuLight ***i:X*** is the only imaging device that provides real-time information on whether a wound is likely to contain elevated levels of PA (>10^4 CFU/g). The ***i:X*** is becoming an essential tool for assisting in clinician decision-making regarding the assessment and treatment of wounds.

"Bacterial removal is a critical component of wound care and wound healing. The ability of the MolecuLight ***i:***X to detect and visualize wounds containing elevated bacterial burden while we are with the patient enables a proactive and objective approach to wound management", says Dot Weir, RN, CWON, CWS, Clinician at Saratoga Hospital Center for Wound Healing and Hyperbaric Medicine, Saratoga Springs, New York and Co-Chair of SAWC, the Symposium on Advanced Wound Care. "Wounds harboring *Pseudomonas* often require unique treatments. This new FDA clearance recognizes the added benefit of the i:X in visualizing and differentiating *Pseudomonas aeruginosa* in wounds through the cyan fluorescence signal it produces on the images. This is especially important because detecting the presence of *Pseudomonas aeruginos*a at the point-of-care allows wound care professionals to act immediately to tailor our cleaning, debridement, antimicrobial strategy and treatments accordingly."

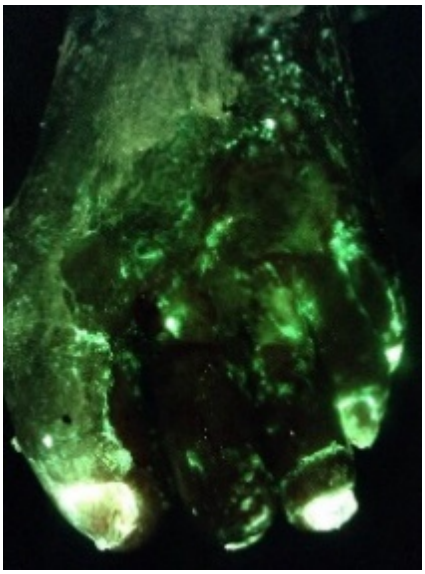

Image and video courtesy of Dot Weir

This video showing the cleansing of a diabetic foot ulcer is an example of the MolecuLight ***i:***X's cyan fluorescence signal indicating the likely presence of PA. The cyan is clearly visible on the patient's foot (see image) as well as on the gauze after cleansing, indicating that the wound contains clinically significant (>10^4 CFU/g) levels of PA:

Video link: https://www.youtube.com/watch?v=X5YiT4zTUL8

References

1. *Raizman et al., "Rapid Diagnosis of Pseudomonas aeruginosa in Wounds with Point-of-Care Fluorescence Imaging", Diagnostics 2021, 11(2), 280*
2. *Turner et al., "Requirements for Pseudomonas aeruginosa Acute Burn and Chronic Surgical Wound Infection", PLoS Genet. 2014, 10, e1004518*
3. *McManus et al., "Twenty-five-year review of Pseudomonas aeruginosa bacteremia in a burn center", Eur. J. Clin. Microbiol. 1985, 4, 219–223*

About MolecuLight Inc.

MolecuLight Inc., a privately-owned medical imaging company that has developed and is commercializing its proprietary fluorescent imaging platform technology in multiple clinical markets. MolecuLight's first commercially released device, the MolecuLight ***i:X*** fluorescence imaging system and its accessories provide a point-of-care handheld imaging device for the global wound care market for the detection of wounds containing elevated bacterial burden (when used with clinical signs and symptoms) and for digital wound measurement. The company is also commercializing its unique fluorescence imaging platform technology for other markets with globally
relevant, unmet needs including food safety, consumer cosmetics and other key industrial markets.

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