Results from 350-Patient FLAAG Trial Show MolecuLight Point-of-Care Imaging Improves Detection of High Bacterial Burden in Wounds Four-fold over Standard of Care Assessment

Study also Demonstrates that MolecuLight Fluorescence Imaging of Bacteria at Point-of-Care Resulted in Changes to Treatment Planning in 69% of All Patient Cases

Toronto, CANADA – (September 29, 2020) MolecuLight Inc., the leader in point-of-care fluorescence imaging for real-time detection of bacteria in wounds, announced publication of results from the *Fluorescence Imaging Assessment and Guidance* ("FLAAG") clinical trial in *Advances in Wound Care*. This large prospective, multicenter, controlled clinical trial included 350 patients, across 14 U.S. outpatient wound care centers and 20 clinicians. The trial, independently led by Dr. Thomas E. Serena and his team at the SerenaGroup®, evaluated whether fluorescence imaging (MolecuLight ***i:X***) improves detection of high (>10^4 CFU/g) bacterial loads when used in combination with clinical signs and symptoms of assessment. The trial also examined how point-of-care information on bacterial presence and location impacted clinical treatment planning. The study, which included diabetic foot ulcers, venous leg ulcers, pressure ulcers and other chronic wounds, revealed that 82% of study wounds had high bacterial burden (>10^4 CFU/g). Use of the MolecuLight ***i:X*** fluorescence imaging device resulted in detection of 45% more wounds with high bacterial loads that wound have otherwise been missed by standard of care assessment of clinical signs and symptoms; these results were consistent across all wound types, study sites and clinicians. The objective, diagnostic information on bacterial load provided by fluorescence imaging changed clinical treatment planning in 69% of wounds and influenced wound bed preparation in 85% of study wounds. Most importantly, clinicians reported that use of fluorescence imaging improved patient care in 90% of study wounds.

"The FLAAG trial, one of the largest prospective clinical trials in wound care, demonstrated that clinical signs and symptoms are poor indicators of bacterial burden in chronic wounds", says Dr. Serena, Founder and Medical Director of The SerenaGroup® and Lead Investigator for the clinical trial. "Most of the wounds missed by standard of care in this study had alarmingly high bacterial loads, indicative of asymptomatic infection. Use of the MolecuLight ***i:X*** enabled earlier detection of bacterial burden in wounds that would have otherwise been missed by standard of care assessment; we saw this improvement in detection across all wound types. The information provided by fluorescence imaging had utility across in all aspects of wound care, influencing treatment planning and overall patient care. I believe that the MolecuLight ***i:X*** will quickly become a standard of care in wound care and play a pivotal role in antimicrobial stewardship in the wound clinic."

"As an investigator in this trial and a user of MolecuLight ***i:X*** in my routine clinical practice, I can attest to the clinical benefit that fluorescence imaging provides. Identifying the presence and location of significant bacteria facilitates optimal preparation and treatment of my patients' wounds enables me to quickly course correct a patient's treatment when needed. With this immediate diagnostic feedback on bacteria and infection available at point-of-care, I no longer need to wait for weeks to determine if treatments are effective", says Dr. Windy Cole, Director of Wound Care Research, Kent State University College of Podiatric Medicine. "The results of this robust clinical trial add to the large body of evidence

from prior studies, including a study I previously published[1] where I used fluorescence imaging of bacteria to guide debridement and select appropriate treatments that led to accelerated wound healing".

Up to 15% of Medicare beneficiaries had at least one type of wound or wound-related infection[2], and the prevalence of chronic wounds continues to increase each year. Without objective methods to detect bacterial burden in wounds, wound healing stalls and inappropriate treatments are applied, further inflating these costs. "Results from this trial reveal the signification proportion of chronic wounds with high bacterial burden that are missed by standard of care assessment of clinical signs and symptoms," says Anil Amlani, CEO of MolecuLight Inc. "The results of this study show how use of point-of-care fluorescence imaging enables more accurate detection of bacterial burden in wounds. The diagnostic information provided by the device has the potential to fundamentally change the paradigm in wound care, leading to improved healing rates, reduced costs and improved patient outcomes".

The early results of this FLAAG trial were shared with the AMA and CMS, who, after a critical review of the large body of supporting clinical evidence, issued two CPT® codes (Category III) for physician work and facility payment for Hospital Outpatient Department (HOPD) and Ambulatory Surgical Center (ASC) settings through an Ambulatory Payment Classification (APC) assignment. These new codes were issued by AMA and CMS in recognition of the medical necessity of this MolecuLight fluorescence imaging procedure.

A video abstract of this publication by Drs. Serena and Cole is available at https://youtu.be/vNX5Ej9mpPA. This publication represents a significant addition to the growing body of evidence on the utility of point-of-care fluorescence imaging of bacteria in wound care.

[1]Cole W and Coe S. *Use of a bacterial fluorescence imaging system to target wound debridement and accelerate healing: a pilot study*. *J Wound Care*. (North American Supplement). 2020

[2.] Nussbaum et al. *An economic evaluation of the impact, cost and medicare policy implications of chronic nonhealing wounds.* *Value in Health* 2018;21:27-32.

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About MolecuLight Inc.

MolecuLight Inc. (www.moleculight.com) is 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 diagnostic tool for the global wound care market for the detection of bacteria and 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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