



PRESS RELEASE
For immediate release

Damae Medical launches a large clinical study to demonstrate the benefit of its deepLive™ imaging device for non-invasive skin cancer diagnosis

- **The deepLive™ non-invasive device, invented by Damae Medical, will be compared to invasive biopsy for the diagnosis of basal cell carcinoma, the most common skin cancer.**
- **900 patients with suspicious skin lesions will participate in the ECOBASO study at eight public hospitals and private dermatology centers in France.**
- **The study is funded by the French government as part of the France 2030 program. This operation is supported by the National Syndicate of Dermatologists and Venereologists (SNDV).**

Paris, France, November 30, 2022 - Damae Medical, a developer of innovative imaging devices and artificial intelligence solutions for diagnostic support for dermatologists, announces the launch of the ECOBASO study: a randomized, prospective, multi-center clinical trial. The objective of this study is to compare the clinical and economic efficacy of the deepLive™ optical biopsy device for the diagnosis of basal cell carcinoma (BCC) compared to invasive biopsy.

Approximately 70,000 cases of BCC are detected each year in France. This figure, which is constantly increasing, represents nearly 70% of all skin cancers. BCC represents a significant burden for the healthcare system and contributes to the saturation of dermatological resources in France, with currently several months of delay to obtain a medical consultation.

By reducing the number of steps required to diagnose BCC, deepLive™ will allow the patient to have an immediate diagnosis and may lead to a reduction in costs for healthcare systems. CE-marked and commercially available since 2020, deepLive™ demonstrated a 12% increase in diagnostic accuracy over dermoscopic examination alone (85% to 97%) in a study of 303 BCC cases. The results of this study, conducted by the Department of Dermatology at the Erasmus Hospital (Brussels), were published in 2022.

900 patients with a skin lesion suspected to be a BCC will participate in the study conducted at eight public and private dermatology centers in France, including Nice University Hospital, Saint-Etienne

University Hospital, Saint-Louis Hospital (AP-HP) as well as private dermatology-venereology specialized care teams. These patients will be followed up at one year. Full results of the trial, which is sponsored by Damae Medical, will be available in the third quarter of 2025.

The study is funded by the French government as part of the France 2030 program "Evaluation of the medical and/or economic benefit of digital or artificial intelligence-based medical devices".

Anaïs Barut, President and co-founder of Damae Medical, said: *"Clinical trials already conducted with deepLive™ have allowed us to demonstrate the performance of our device, in BCC, as well as in other types of skin cancers (melanoma, squamous cell carcinoma). With the ECOBASO study, we are evaluating the medico-economic value of our innovation and the conditions for the coverage of procedures performed with deepLive™, today the most advanced technology in the world for the non-invasive diagnosis of skin cancers."*

Prof. Philippe Bahadoran, President of the Non-Invasive Skin Imaging Group of the French Society of Dermatology, said: *"Basal cell carcinoma (BCC) is by far the most common skin cancer. It is the cause of significant morbidity for patients and a significant medical and economic impact on society.*

When the clinical diagnosis is uncertain, when the removal of the BCC requires a major surgical procedure or a cosmetic risk (facial lesions) or when one wishes to propose a non-surgical treatment, it is necessary to have a biopsy beforehand. This increases morbidity and lengthens the time it takes to take care of the disease, ultimately leading to a significant additional cost.

The deepLive™ medical device, which allows a non-invasive and rapid diagnosis of BCCs, with excellent performance, could be an attractive alternative to biopsy. The randomized, prospective, multicenter ECOBASO study comparing the deepLive™ medical device to biopsy will, if positive, have a major impact on the management of BCCs."

Dr. Luc Sulimovic, President of the National Syndicate of Dermatologists and Venereologists said: *"Innovation in the field of imaging opens up important perspectives in dermatology. The challenge of the ECOBASO study and the purpose for which it was designed is to enable the adoption of this technology by private dermatologists but also by all private and public actors, in order to improve the care pathway for all patients, throughout the territory through the Specialized Care Teams in dermatology-venereology."*

About Damae Medical

Damae Medical is reinventing skin imaging, revolutionizing the screening, management, and follow-up of skin cancers (melanoma and carcinoma) with its deepLive™ solution, which provides an accurate, fast and reliable optical examination without performing a biopsy.

CE marked, the deepLive™ medical device is based on LC-OCT (Line-field Confocal Optical Coherence Tomography) proprietary optical imaging technology that provides 3D images of the different layers of the skin at the cellular level, complemented by several software and Artificial Intelligence (AI) modules.

This innovation is protected by 6 patent families and has already been published in more than 50 scientific and medical publications.

Present in 10 countries and used in more than 30 referral centers, deepLive™ transforms the daily practice of dermatologists making the management of skin pathologies efficient, reassuring, and non-invasive for the patient. The product is also used by leading cosmetic and pharmaceutical players for research and evaluation purposes.

Based in Paris, Damae Medical currently employs 25 people. Winner of several innovation awards (MIT Technology Review, Bpifrance, European Commission), the company has been able to invest more than €20 million since its creation in 2014.

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