PRESS RELEASE

US Food and Drug Administration (FDA) grants Breakthrough Device status to Guerbet innovation: DUOnco™ Pancreas for early detection of pancreatic lesions

A major improvement in early cancer detection using AI to increase incidental discoveries of cancer at a stage when it is still resectable.

Villepinte France, February 30th, 2025: Guerbet (FR0000032526 GBT), a world leader in medical imaging solutions, today announced that the US Food and Drug Administration (FDA) has granted "Breakthrough Device" designation to DUOnco™ Pancreas for which Intrasense (ISIN: FR0011179886 - Mnemo: ALINS), a French expert in AI-enhanced medical imaging solutions facilitating and securing diagnosis, decision-making and therapeutic follow-up, will be the legal manufacturer.

DUOnco™ Pancreas is a reading and analysis software designed to help radiologists detect focal lesions and dilation of the pancreatic duct on portal venous phase CT scans, signs of pancreatic cancer. It is indicated for adult patients undergoing contrast-enhanced CT scans containing the pancreas.

DUOnco™ Pancreas - for opportunistic detection thanks to AI

DUOnco™ Pancreas is designed to detect pancreatic lesions by analyzing CT scans initially acquired for a variety of clinical purposes.
This incidental approach is expected to improve identification of patients with often asymptomatic, early-stage pancreatic cancer, potentially increasing the number of patients eligible for surgery.

DUOnco™ Pancreas does not replace radiologists, it acts as a safety net by reducing cognitive load and stress. By helping to identify subtle pancreatic lesions, it boosts diagnostic confidence and supports radiologists' performance in highly demanding clinical environments, while potentially reducing legal risk for medical institutions.

"DUOnco™ Pancreas is a tool designed to integrate our daily CT (computed tomography / tomodensitometry) practices, to reduce the stress associated with the fear of not detecting pancreatic cancer; and ultimately improve patient benefit".
Pr Vullierme, Oncoradiologist (Hôpital Paul Brousse AP-HP France).

At present, there are no FDA-approved solutions focused on detecting incidental findings of pancreatic cancer.
The FDA Breakthrough designation is awarded to medical devices that enable more effective treatment or diagnosis of life-threatening or irreversibly disabling diseases or conditions[1].
This designation accelerates the development, evaluation and revision of the medical devices concerned, thanks to priority support from the FDA.
DUOnco™ Pancreas is ideally positioned to meet a major clinical need, with the hope of helping to save lives by increasing the number of patients eligible for surgery.

Contact :

Matthieu BRUNEAU - Global corporate communication manager
Email : matthieu.bruneau@guerbet.com
Phone : +33 6 78 83 89 96

"We are extremely honored to receive breakthrough device designation from the FDA for DUOnco™ Pancreas. This recognition underscores our commitment to innovate to improve early detection of pancreatic cancer and, ultimately, to save lives. Thanks to this breakthrough, we hope to offer patients a better chance of curative treatment, and support healthcare professionals in their daily practice,"
said **Francois Nicolas, SVP Research, Development, Innovation and AI.**

Pancreatic cancer screening: a major unmet clinical need

In the United States, pancreatic cancer remains one of the most deadly cancers. By 2025, epidemiological estimates predict that approximately 67,440 people will be diagnosed with pancreatic cancer, and 51,980 will die from the disease[2].

Pancreatic cancer has one of the poorest prognoses of all cancers, with a five-year survival rate of just 9%[3] [4]. Surgery remains the only potential curative option, but it is only possible at an early stage. Due to the absence of specific symptoms, less than 20% of patients can benefit from surgery at the time of diagnosis, as most cases are detected too late[5].

Recent studies indicate that CT scans can reveal early signs of pancreatic cancer up to 36 months before clinical diagnosis, providing a valuable window for earlier detection and intervention[6].

Detection performance verified by studies

DUOnco™ Pancreas has been the subject of evaluation studies to confirm its performance.

A clinical study highlighted the software's accuracy[7] :
The area under the curve of the model detecting the presence of lesions in a patient is 0.98, with a sensitivity of 0.94 and a specificity of 0.95. Similar values were obtained for patients with small, isodense lesions.

1 https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program
2 American Cancer Society
3 *Gupta, R., Amanam, I. & Chung, V. Current and future therapies for advanced pancreatic cancer. J. Surg. Oncol. 116(1), 25–34 (2017)*
4 Siegel, R. L., Miller, K. D. & Jemal, A. Cancer statistics, 2019. *CA Cancer J. Clin.* 69(1), 7–34 (2019)
5 Blackford et Al. Recent Trends in the Incidence and Survival of Stage 1A Pancreatic Cancer/ A Surveillance, Epidemiology, and End Results Analysis. 2020.
6 Prevalence, features, and explanations of missed and misinterpreted pancreatic cancer on imaging: a matched case–control study, 2022
7 Abi Nader et al. Automatic Detection of Pancreatic Lesions and Main Pancreatic Duct Dilatation on Portal Venous CT Scans Using Deep Learning, 2023

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About Guerbet

Guerbet is a global leader in medical imaging, dedicated to improving patient care through innovation. With nearly a century of expertise, the company offers a comprehensive portfolio of pharmaceutical products, medical devices, and AI-driven solutions for diagnostic and interventional imaging. Guerbet invests 9% of its annual revenue in research and development, with dedicated innovation centers in France and the United States. The company (GBT) is publicly traded on Euronext Paris and reported €841 million in revenue in 2024.

For more information, visit: www.guerbet.com

Media Contact:

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