Intrasense and Guerbet announce PMDA certification in Japan for DUOnco™ Pancreas, an AI software designed to support the reading of pancreatic areas on contrast-enhanced CT

Montpellier, Villepinte, June 8th 2026 05:45 pm. Intrasense (ISIN: FR0011179886 – Mnemo: ALINS), a French expert in AI-enhanced medical imaging solutions facilitating diagnosis, decision-making and therapeutic follow-up, and **Guerbet (FR0000032526 GBT),** a global leader in medical imaging, announce that DUOnco™ Pancreas has obtained PMDA certification in Japan under certification number 308AGBZI00003000 (Class II, Classification: Program 1 Disease Diagnostic Program, Program for X-ray imaging diagnostic device workstations (JMDN code: 40935012)). With this certification, **DUOnco™ Pancreas becomes to our knowledge the first AI software focused on the pancreas to be certified in Japan.**

A major unmet medical need in Japan

Pancreatic cancer remains one of the deadliest malignancies worldwide and represents a particularly important healthcare challenge in Japan. In 2022, 510,992 new cases and 467,409 deaths were estimated worldwide, including 47,627 new cases and 43,265 deaths in Japan. Japan ranked among the countries with the highest incidence and mortality burden for this disease[1].

Surgery remains the only potentially curative treatment, but it is generally possible only when the disease is identified at an early stage. Early pancreatic cancer often causes few or no specific symptoms, and lesions can be difficult to identify on CT because of their small size and limited contrast. Because many patients are diagnosed after progression, fewer than 20% are eligible for surgery[2]

Prior studies have also reported that 42% of pancreatic cancers smaller than 2 cm were missed on CT, underlining the need for tools that may help radiologists identify subtle findings earlier[3].

Published data including a recent project led by Guerbet's research team[4] in collaboration with researchers from the University of Copenhagen, suggest that characteristic CT findings of pancreatic cancers are visible as early as 36 months before diagnosis, indicating an opportunity for earlier detection.

AI software designed to support radiologists, not replace them

DUOnco™ Pancreas is an AI-based image analysis software designed to assist radiologists in the evaluation of contrast-enhanced CT examinations by highlighting regions of interest in the pancreas. The software is intended to support the detection of regions of interest in the pancreas, the measurement of these areas and the main pancreatic duct maximal size.

1 World Cancer Research Fund

2 Blackford et Al. Recent Trends in the Incidence and Survival of Stage 1A Pancreatic Cancer/ A Surveillance, Epidemiology, and End Results Analysis. 2020.

3 Factors associated with missed and misinterpreted cases of pancreatic ductal adenocarcinoma

4 Validation of a Pretrained Artificial Intelligence Model for Pancreatic Cancer Detection on Diagnosis and Prediagnosis Computed Tomography Scans. 2026.

DUOnco™ Pancreas is designed to support radiologists in their routine reading workflow. It is not an automated diagnostic system and does not replace physician review, interpretation, or diagnosis.

Seamless integration into existing viewing environments

In Japan, Intrasense and Guerbet intend to work closely with local imaging IT partners to integrate DUOnco™ Pancreas as tightly as possible into radiologists' existing reading environments, especially through collaboration with PACS vendors and other established system providers.

This strategy is intended to provide the best possible user experience by enabling radiologists to access the software within their habitual viewer and routine workflow, while limiting disruption and facilitating adoption in daily practice.

Continued investment in clinical research in Japan and Europe

This certification in Japan is part of a broader effort by Guerbet and Intrasense to evaluate the clinical value of pancreas-focused AI through research collaborations in Japan and Europe.

Among these initiatives is the research collaboration with Kyushu University Hospital, announced by Guerbet in April 2025, to assess the performance of DUOnco™ Pancreas using a substantial dataset including a majority of Japanese patients and cases of early pancreatic cancer. Kyushu University Hospital is recognized for its expertise in pancreatic cancer imaging[5].

Professor Kousei Ishigami, from Kyushu University Hospital, commented: *"By utilizing this AI, incidental detections in the pancreas are expected to increase, potentially enabling cancer treatment at an earlier stage."*

A new step in the international development of DUOnco™ Pancreas

The certification in Japan builds on the CE marking already obtained in Europe in 2025 for DUOnco™ Pancreas, which represented a key milestone in the DUOnco™ roadmap co-developed by Intrasense and Guerbet[6]. The product also received "Breakthrough Device designation" from the FDA in the United States in 2025[7] which does not represent marketing approval, reflecting its potential to address a global unmet need in medical imaging.

Stephen Armand, CEO of Intrasense, commented: *"One of our objectives is to work in tight collaboration with local partners to integrate our software in their ecosystem and provide the smoothest possible usage experience to Japanese radiologists. We also would like to thank M3, Inc. who supported in obtaining the certification and to MEDISCIENCE PLANNING, Inc. who acts as our DMAH."*

François Nicolas, SVP Research, Development, Innovation and AI at Guerbet commented: *"Built on insights from extensive local user research involving more than 100 medical institutions in Japan, our software is purposefully designed to meet the expectations of Japanese radiologists."*

5 Press release Guerbet and Kyushu university study announcement

6 Press release CE mark obtention

7 Press release FDA Breakthrough Device status obtention

Next event: 2026 half-year revenue: July 23 (after market close)

About Intrasense

A French expert in medical imaging since 2004 and a digital subsidiary of the Guerbet Group, Intrasense designs medical imaging software solutions natively enriched by artificial intelligence algorithms.

Myrian®, an advanced radiology visualization platform featuring cutting-edge clinical tools, optimizes and simplifies the interpretation of all types of images. DUOnco™, a range of expert AI algorithms for oncology, offers an AI for the detection of focal liver lesions and the first AI dedicated to CE-marked bone lesions. Liflow®, a dedicated oncology monitoring solution integrating multi-organ AIs, optimizes the longitudinal monitoring of cancer patients.

By combining clinical expertise and operational performance, Intrasense provides healthcare professionals with high medical value tools, facilitating analysis, diagnosis and patient management.

More information on www.intrasense.fr

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About Guerbet

At Guerbet, we build lasting relationships so that we enable people to live better. That is our purpose. We are a global leader in medical imaging, offering a comprehensive range of pharmaceutical products, medical devices, and digital and AI solutions for diagnostic and interventional imaging. As pioneers in contrast products for 100 years, with 2,746 employees worldwide, we continuously innovate and devote 10% of our revenue to Research and Development in four centers in France and the United States. Guerbet (GBT) is listed in Compartment B of Euronext Paris and generated revenue of €786 million in 2025.

For more information, please visit: **www.guerbet.com**