

**FOR IMMEDIATE RELEASE**

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## **New Indication Approved for Verdye (Indocyanine Green for Injection, ICG) for Breast Sentinel Lymph Node Mapping**

**DIAGNOSTIC GREEN LTD, ATHLONE, IRELAND** – Diagnostic Green Ltd. (Diagnostic Green) is pleased to announce the approval of Verdye (ICG) for intraoperative identification of sentinel lymph nodes and visualisation pathways in breast cancer in Spain.

The presence of lymphatic metastases is an important prognostic factor for the survival of breast cancer. Sentinel lymph node biopsy (SLNB) continues to be a fundamental component of early breast cancer and is the current standard of care to help determine whether cancer has spread to the lymph nodes.

With the approval of ICG for breast SLNB, surgeons now have an alternative to using Technetium (99mTc) radio-labelled colloids with blue dyes (BD) to visualise lymph nodes. Using 99mTc is a significant burden for both patients as well as hospitals which includes logistical challenges associated with pre-procedure administration, the risk of exposure to ionizing radiation for professionals and all the requirements associated with radiopharmaceutical handling. Additionally, blue dyes can pose significant potential risks including soft tissue necrosis, metabolic and hematologic side effects, making it infrequently utilised for routine surgical care.

In discussing the approval, Declan Cassells, Managing Director of Diagnostic Green stated that, "This is a great advancement for breast SLN detection, leveraging the real-time imaging capabilities ICG. The intraoperative use of ICG not only matches or surpasses the accuracy of current approaches but also notably improves the patient experience, offering a safer and less invasive alternative to traditional methods involving Technetium and blue dyes for SLN detection."

The approval was supported by multiple meta-analyses studies which concluded that

- ICG-fluorescence (ICG-F) **is superior to BD** staining in every metric of breast SLN detection
- ICG-F is **non-inferior to both radioisotope (RI)-lymphoscintigraphy and the combination of RI + BD** in per-case SLN detection and both per-case and per-node sensitivity/false negative rate (FNR)

- ICG-F is ***superior to both RI and RI+BD in per-node SLN detection***

Verdye (Indocyanine Green, ICG) is available throughout EMEA and sold through a network of distributors or directly by Diagnostic Green. For information on how to order Verdye (Indocyanine Green) in specific territories, please check out <https://diagnosticgreen.com/row/distributor-details/> or contact Diagnostic Green at [info@diagnosticgreen.com](mailto:info@diagnosticgreen.com)

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Diagnostic Green Ltd. is a wholly owned subsidiary of Renew Health Ltd. Based in Ireland, Diagnostic Green is the leading provider of Indocyanine Green worldwide. The product is sold as Verdye across the EMEA and Latin America, and as Indocyanine Green for Injection, USP in the USA and Canada. Diagnostic Green was established to provide high quality fluorescence imaging products to physicians worldwide. Our vision is to ensure that fluorescence imaging becomes the standard in tissue visualisation for physicians in every operating room/theatre worldwide.

For more information go to [www.diagnosticgreen.com](http://www.diagnosticgreen.com)