

FOR IMMEDIATE RELEASE

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

ATHLONE, IRELAND – Diagnostic Green Ltd (Diagnostic Green) is pleased to announce the approval of Verdye (Indocyanine Green, ICG) for ***intraoperative identification of sentinel lymph nodes and visualisation pathways in breast cancer across Europe*** including Austria, Belgium, Croatia, Czechia, Denmark, Finland, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Portugal, Romania, Slovenia, Sweden and the UK. Verdye has previously been approved for the breast SLN indication in Spain.

Sentinel lymph node biopsy (SLNB) remains a cornerstone in the management of early-stage breast cancer, serving as the standard of care to determine the presence of lymphatic metastasis—one of the most critical prognostic indicators of disease progression.

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 radio-pharmaceutical 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.

ICG-guided fluorescence imaging addresses these limitations by providing ***real-time, high-contrast visualisation*** of sentinel lymph nodes without the need for radioactive materials or toxic dyes.

“This approval marks a significant step forward in breast cancer surgery,” said **Declan Cassells, Managing Director of Diagnostic Green**. “ICG not only meets or exceeds the accuracy of traditional techniques but also enhances patient safety and optimises intraoperative workflow. We are proud to offer a solution that makes SLNB safer, simpler, and more accessible.”

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 across the EMEA region via a network of authorised distributors or directly from Diagnostic Green.

To order or learn more, please visit: <https://diagnosticgreen.com/row/distributor-details/>
Or contact us at: **info@diagnosticgreen.com**

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Diagnostic Green Ltd is a wholly owned subsidiary of Renew Pharmaceuticals 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 IC-Green® (indocyanine green for injection), in the USA. 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