

Zydus announces Final Approval from the USFDA for Indocyanine Green for Injection with 180-Days CGT exclusivity

Plans to launch the product shortly triggering 180-Days CGT exclusivity period

Ahmedabad, India / Pennington, New Jersey, 4 August 2026

Zydus Lifesciences Limited (Zydus) announces the receipt of final approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Indocyanine Green for Injection, USP, 25 mg/vial, a sterile lyophilised powder for reconstitution. Zydus' Indocyanine Green for Injection is the generic equivalent of the reference listed drug (RLD), IC-Green® by Diagnostic Green LLC. The USFDA has designated the application a Competitive Generic Therapy (CGT). Eligibility for the 180-day exclusivity available to certain competitive generic therapies is determined by the USFDA and, where it applies, the period runs from the date of first commercial marketing.

Indocyanine Green for Injection is an optical imaging agent indicated for fluorescence imaging of vessels, blood flow and tissue perfusion before, during and after vascular, gastrointestinal, organ transplant, plastic, micro and reconstructive surgeries, including general minimally invasive surgical procedures; fluorescence imaging of extrahepatic biliary ducts; fluorescence imaging of lymph nodes and lymphatic vessels during lymphatic mapping in adults with cervical and uterine cancer; and ophthalmic angiography. The product is indicated in adults and, for certain indications, in paediatric patients aged 1 month and older.

The product will be manufactured at the group's USFDA-approved injectable manufacturing plant at Jarod, near Vadodara in Gujarat, and will be marketed in the US market by Zydus Pharmaceuticals (USA) Inc.

Speaking on the development, Dr. Sharvil Patel, Managing Director, Zydus Lifesciences Limited, said, "Indocyanine green sits at the intersection of medicine and imaging science, requiring precise control of chromophore purity, photostability and lyophilisation. Developing and securing approval for such a complex product with our partner reflects the capabilities we have built and our shared commitment to high standards. It also advances our goal of making essential medicines and diagnostics more accessible, while strengthening our presence in the functional dye and imaging agent segment, where we continue to invest."



**PRESS
RELEASE**

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The Corporate Communications Department

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CIN : L24230GJ1995PLC025878

The approval adds to the group's portfolio of complex injectable and imaging products, and reflects a development model applied across that portfolio: internal formulation and analytical capability combined with an external partner selected for the particular programme. Zydus continues to invest in the functional dye and imaging agent segment.

The product will be supplied as a kit containing single-patient-use vials of Indocyanine Green for Injection, 25 mg, as a sterile, lyophilized green powder for reconstitution, together with single-dose vials of Sterile Water for Injection, 10 ml.

The brand product had annual sales of approximately USD 125.8 mn in the United States, a growth of 61.0%, with volumes of 0.64 mn units, a growth of 27.1% (IQVIA MAT June-2026).

The Group now has 445 approvals and has so far filed 513* ANDA with the USFDA. (*As on 30-June-2026)

About Zydus

Zydus Lifesciences Ltd., with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global life sciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 30,000 people worldwide, including 1,500 scientists engaged in R & D, and is driven by its mission to unlock new possibilities in life sciences through quality healthcare solutions that impact lives. The group aspires to transform lives through pathbreaking discoveries. Over the last decade, Zydus has introduced several innovative, first-in class products in the market for treating unmet healthcare needs with vaccines, therapeutics, biologicals, and New Chemical Entities. For more details visit www.zyduslife.com

Important Safety Information

Contraindications: Indocyanine Green for Injection, USP is contraindicated in patients with a history of hypersensitivity to indocyanine green.

Warnings and Precautions: Serious hypersensitivity reactions, including anaphylaxis, have been reported in patients with and without a history of allergy to iodides. The product contains sodium iodide and should be used with caution in patients with a history of iodide allergy. Cardiopulmonary resuscitation personnel and equipment should always be readily available, and patients should be monitored for hypersensitivity reactions.

Drug Interactions: Preparations containing sodium bisulfite reduce the absorption peak of indocyanine green in blood and should not be used as an anticoagulant for the collection of samples for analysis. Certain other agents may affect indocyanine green measurements; see the full Prescribing Information.

Adverse Reactions: Adverse reactions identified during post-approval use include hypersensitivity reactions, anaphylaxis, hypotension and injection site reactions.

This is not a complete summary of the safety information for this product, and the statements above are qualified in their entirety by the approved labelling. To report suspected adverse reactions, contact USFDA at 1-800-FDA-1088 or



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www.fda.gov/medwatch.

Forward-looking statements

Certain statements in this release, including statements concerning commercial availability, launch timing, distribution and supply arrangements, regulatory exclusivity and future product development, are forward-looking statements. They involve known and unknown risks and uncertainties, including regulatory action, litigation, intellectual property developments, manufacturing and supply variables, competitive intensity, pricing pressure and general market conditions. Actual outcomes may differ materially from those expressed or implied. Zydus undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

IC-GREEN® is a registered trademark of its respective owner. The reference is made solely to identify the reference listed drug and does not imply any affiliation with, sponsorship by, or endorsement by the trademark owner. Statements in this release relating to the product are limited to its approved labelling; no use outside the approved labelling is described or intended.



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