

Provepharm receives FDA marketing approval in US for BLUDIGO, its indigo carmine injection drug product

BLUDIGO™ first indigotindisulfonate sodium, USP, injection drug product approved by FDA

Marseille, France and Collegeville, PA, USA – July 12, 2022 – Provepharm, a French company specialized in the development of pharmaceutical applications, today announces that it has received FDA New Drug Approval for the marketing of BLUDIGO™, its indigo carmine injectable (Indigotindisulfonate Sodium) drug product. BLUDIGO is a diagnostic dye indicated for use as a visualization aid in the cystoscopic assessment of the integrity of the ureters in adults, following urological and gynecological open, robotic or endoscopic surgical procedures.

“BLUDIGO is the second Provepharm product to obtain marketing authorization from the FDA,” said Frederick Girard, chief medical officer at Provepharm. “This new success validates our strategy, based on a high level of investment in R&D, aimed at improving, on a daily basis, patients’ lives and healthcare professionals’ work.”

“We are very proud of this achievement,” said Michel Féraud, president and founder of the Provepharm group. “In 2016, we were the first to register a methylene blue injection product in the US and I am happy that our newly approved BLUDIGO drug product will also soon be available to US patients.”

This additional approval is a clear validation of the group’s worldwide strategy, implemented through its operations in both Europe and the United States. It aims to develop new medicines and diagnostic products from known molecules, to respond to unmet medical needs and to reset drugs in different indications, in this case, the intraoperative assessment of the ureter’s integrity.

About the intraoperative assessment of the ureter’s integrity

Iatrogenic damage of the ureters (the ducts carrying urine from kidney to bladder), can occur during urological and gynecological surgery. [Eighty-two percent of ureter injuries are caused during pelvic surgery and 75% of urinary tract injuries are due to gynecologic surgery.](#) Current estimates of urinary tract injury incidence with all types of gynecologic surgery range from [0.2 to 15 per 1,000 cases](#). If the damage is not identified during the surgical procedure, it may lead to severe post-surgical complications, notably obstruction fistulas and sepsis, with potential impact on the functional prognosis of the kidney and sometimes on the vital prognosis. These complications also lead to the need for a reintervention, sometimes as an emergency. Hence, screening for potential iatrogenic ureteral damage during the intervention can provide surgeons with an opportunity to repair the damage



Press release

immediately, which may significantly contribute to the reduction of post-surgical complications.

About BLUDIGO

BLUDIGO™ is an injectable dye indicated as a visualization aid in the cystoscopic assessment (through bladder endoscopy) of the integrity of the ureters in adults following urological and gynecological open, robotic or endoscopic surgical procedures.

About Provepharm

Provepharm Life Solutions is an independent French pharmaceutical company acting internationally, specializing in molecule revitalization. Its long-standing expertise in fine chemistry and high investment in R&D enables it to reset the purity of active pharmaceutical ingredients to the highest standards, for the development of drug products and medical devices. Provepharm's strategy has already proven successful through the patented development and approval of a methylene blue injection, notably in the European Union and the United States of America.

Provepharm is dedicated to improving the life of those patients who benefit from its innovative products. The company also values quality of life at work, committing entirely to improving conditions for its staff. Provepharm also looks for ways to be more engaged in its ecosystem through CSR programs and a dedicated endowment fund.

For more information, visit www.provepharm.com or follow us on [LinkedIn](#).

Contact Provepharm	Media Contact
Julie WAGNER Communication officer julie.wagner@provepharm.com Mobile : +33 (0)6 68 78 65 18	Andrew Lloyd & Associates Juliette Schmitt - juliette@ala.com Emilie Chouinard - emilie@ala.com Tel.: +33 (0)1 56 54 07 00 @ALA_Group