

Photocure and Intelligent Scopes Corporation partner on development of AI for blue light cystoscopy

Press Release – Oslo, Norway, October 15, 2025: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that it has entered into a partnership with Intelligent Scopes Corporation (ISC) to develop Artificial Intelligence (AI) software with blue light cystoscopy (BLC®). Initial testing shows promising performance results.

Photocure and ISC have signed a development agreement on AI software and BLC for the detection of bladder tumors. Photocure is a pioneer in the bladder cancer diagnostics market with its Hexvix[®]/Cysview[®] products, supported by robust clinical evidence and treatment guidelines. ISC, based in the U.S., is a subsidiary of Claritas HealthTech Limited, based in the UK. Claritas and its affiliates, together with ISC, develop leading endoscopy solutions that ISC commercializes.

In the current development phase, Photocure and ISC are collaborating to develop an AI software which can support the physician in real-time during blue light cystoscopy, improving early-stage bladder cancer detection, diagnosis, and resection completeness. The initial testing results were based on approximately 200 blue light procedures with more than 80,000 images. These results support the benefits of AI enabled blue light cystoscopy by detecting high risk cancerous lesions earlier in the patient pathway and more accurately.

Photocure will support the development collaboration through an initial clinical study, with the aim to collect blue light videos and images from bladder cancer patients, at multiple sites in the U.S. and Europe, to train the blue light AI software. Details of the study (ENAiBLE) can be found on clinicaltrials.gov (http://clinicaltrials.gov/study/NCT07144319).

Upon completion of the development, Photocure and ISC intend to pursue FDA clearance for the AI software compatible with any blue light cystoscope system. Regulatory clearances will be pursued in parallel across Europe and other markets. The next milestone would be the beta-version of the new Blue light AI detection software within 12-18 months, ahead of regulatory review.

Based on the terms of the agreement, Photocure will have exclusive, perpetual rights to commercialize the new solution via its direct sales force, distributors or partners, as well as license to device manufacturers in any given country upon regulatory clearance.

"Our partnership with ISC is part of Photocure's strategic focus on advancing precision diagnostics in uro-oncology. Building on its strong track record and established credibility in bladder cancer diagnostics, Photocure aims to leverage leading innovative technologies to grow a portfolio of complementary diagnostic solutions to address the evolving needs of patients, physicians, and the broader healthcare community. This initiative underscores Photocure's commitment to drive the progress towards more personalized and data-driven management in uro-oncology, enabling better clinical outcomes. Recent publications indicate that the global AI cancer diagnostic market is experiencing significant growth due to the rising prevalence of cancer, increasing demand for precision diagnostics to increase accuracy, and a growing awareness for the importance of early and more precise diagnosis. BLC has become the reference point for next-generation cystoscopy technologies — it is not just enhancing what we see, but also redefining what is possible in detecting previously easy to miss but aggressive disease. We envision that ISC's AI technology will support transforming diagnostic approaches using BLC and will create a strategic shift towards integrated precision medicine," said Dan Schneider, President and CEO of Photocure.

Dr. Rajesh Nair, Urological Surgeon at Guy's and St. Thomas', UK, and Chief Medical Officer at ISC, commented, "As a practicing bladder cancer surgeon, where I regularly face the challenge of accurate detection and complete resection of tumors, I am excited about the prospect of a new solution that combines ISC's proven track record in state-of-the-art AI solutions for cystoscopy with the detection capabilities of blue light cystoscopy that Photocure provides. With the evidenced improvement in accuracy achieved with ISC's existing AI technology for bladder tumor detection, the application of its cutting-edge technology together with the enhanced detection capability of blue light cystoscopy from Photocure marks a significant leap forward in bladder cancer diagnostics with the potential to transform bladder cancer management, significantly enhancing patient care and outcomes."

"The integration of AI will ensure BLC continues to out-perform white light cystoscopy, as initial performance data indicate blue light AI has the potential to detect more tumors, especially high-grade flat carcinoma in situ (CIS) lesions, than white light AI. However, assisting urologists in the detection of tumors with AI-enhanced blue light cystoscopy is just a first development step. We also intend to explore the blue light AI software to assist with real-time tumor characterization and mapping of CIS lesions for enhancing risk stratification and precision monitoring. Such additional aims expand the utility of our technology to further help urologists achieve their bladder cancer management goals with BLC. These next iterations could drive practice-changing applications that blue light cystoscopy can uniquely deliver," said Anders Neijber, Chief Medical Officer of Photocure.

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About Bladder Cancer

Bladder cancer ranks as the 8th most common cancer worldwide – the 5th most common in men – with 1 949 000 prevalent cases (5-year prevalence rate)^{1a}, 614 000 new cases and more than 220 000 deaths in 2022.^{1b}

Approx. 75% of all bladder cancer cases occur in men.¹ It has a high recurrence rate with up to 61% in year one and up to 78% over five years.² Bladder cancer has the highest lifetime treatment costs per patient of all cancers.³

Bladder cancer is a costly, potentially progressive disease for which patients have to undergo multiple

cystoscopies due to the high risk of recurrence. There is an urgent need to improve both the diagnosis and the management of bladder cancer for the benefit of patients and healthcare systems alike. Bladder cancer is classified into two types, non-muscle invasive bladder cancer (NMIBC) and muscle-invasive bladder cancer (MIBC), depending on the depth of invasion in the bladder wall. NMIBC remains in the inner layer of cells lining the bladder. These cancers are the most common (75%) of all BC cases and include the subtypes Ta, carcinoma in situ (CIS) and T1 lesions. In MIBC the cancer has grown into deeper layers of the bladder wall. These cancers, including subtypes T2, T3 and T4, are more likely to spread and are harder to treat.⁴

About Hexvix®/Cysview® (hexaminolevulinate HCI)

Hexvix/Cysview is a drug that preferentially accumulates in cancer cells in the bladder, making them glow bright pink during Blue Light Cystoscopy (BLC®). BLC with Hexvix/Cysview, compared to standard white light cystoscopy alone, improves the detection of tumors and leads to more complete resection, fewer residual tumors, and better management decisions.

Cysview is the tradename in the U.S. and Canada, Hexvix is the tradename in all other markets. Photocure is commercializing Cysview/Hexvix directly in the U.S. and Europe and has strategic partnerships for the commercialization of Hexvix/Cysview in China, Chile, Australia, New Zealand and Israel. Please refer to http://photocure.com/partners/our-partners for further information on our commercial partners.

The following safety information is solely included to comply with U.S. regulatory requirements: Important Risk & Safety Information for Cysview® (hexaminolevulinate HCl)

About Photocure ASA

Photocure: The Bladder Cancer Company delivers transformative solutions to improve the lives of bladder cancer patients. Our unique technology, making cancer cells glow bright pink, has led to better health outcomes for patients worldwide. Photocure is headquartered in Oslo, Norway and listed on the Oslo Stock Exchange (OSE: PHO). For more information, please visit us at www.photocure.com/news.

About Intelligent Scopes Corporation

Intelligent Scopes Corp provides state-of-the-art image processing and enhancement software medical devices and AI diagnostic tools for the fields of urology and gastroenterology. The company focuses on the strategic R&D of image processing, image enhancement, AI diagnostic tools, and robotic guidance systems for endoscopy procedures to improve detection rates, reduce unnecessary biopsies and enhance patient outcomes. For more information, please visit: www.intelligentscopes.com.

About Claritas HealthTech Limited

Claritas conducts research and development in the fields of image enhancement, machine vision and artificial intelligence ("AI") with a focus on medical image processing and AI-assisted interpretation and diagnostics. Claritas aims to transform the diagnostics industry with powerful and effective software products created using image enhancement and AI technology, to enable and assist doctors in medical diagnostics. For more information, please visit www.claritashealthtech.com.

For further information, please contact:

Dan Schneider President and CEO Photocure ASA

Email: ds@photocure.com

Erik Dahl CFO Photocure ASA

¹ Globocan. a) 5-year prevalence / b) incidence/mortality by population. Available at: http://gco.iarc.fr/today, accessed [February 2024].

² Babjuk M, et al. Eur Urol. 2019; 76(5): 639-657

³ Sievert KD et al. World J Urol 2009;27:295–300

⁴ Bladder Cancer. American Cancer Society. http://www.cancer.org/cancer/bladder-cancer.html

Tel: +4745055000

Email: ed@photocure.com

Priyam Shah Vice President Investor Relations Tel: +17176815072

Email: priyam.shah@photocure.com

Media and IR enquiries:

Geir Bjørlo

Corporate Communications (Norway)

Tel: +47 91540000

Email: geir.bjorlo@corpcom.no