



THE
BLADDER CANCER
COMPANY

Bladder Cancer technology: New improved Blue Light Cystoscopy system receives FDA approval for use in NMIBC in the U.S.

Oslo, Norway, February 7, 2022: Photocure ASA, The Bladder Cancer Company, announces U.S. Food and Drug Administration (FDA) approval of a new and improved Blue Light system to be used with Photocure's Cysview® product in Blue Light Cystoscopy (BLC®) procedures for the detection of NMIBC*. Manufactured and soon to be commercialized by KARL STORZ Endoscopy-America, Inc. (KARL STORZ), the new Blue Light system is approved for use in procedures requiring rigid cystoscopy. FDA approval was granted to KARL STORZ on February 4, 2022.

"The successful FDA approval is great news for the bladder cancer community in the U.S.," commented Geoffrey Coy, Vice President and General Manager, North America at Photocure. "In healthcare, constant technical innovation is crucial, and we expect that this new, enhanced BLC system will fulfill our clients' expectations for improving the Blue Light experience. The new system is the next generation and includes practical features to make the technology more user friendly. We look forward to expanding the use of BLC with Cysview®," Geoffrey Coy concluded.

"At KARL STORZ, we are committed to helping our customers deliver top-quality care, and we believe that our new Blue Light system demonstrates this commitment," said Michael Lyman, Executive Director, Sales & Marketing, Urology and Gynecology, KARL STORZ Endoscopy-America. "The New Blue Light Powered by Saphira® will allow us to serve the needs of our customers, providing next-level visualization to enable the right solutions for urological procedures in patients with Non-Muscle Invasive Bladder Cancer and continue our collaboration with the Photocure team to make high-quality BLC available to more patients in the U.S."

Photocure expects to inform its stakeholders about the launch of the new Blue Light system as KARL STORZ provides further information regarding the product and its launch plans.

*NMIBC: non-muscle invasive bladder cancer

Note to editors

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About Bladder Cancer

Bladder cancer ranks as the seventh most common cancer worldwide, with 1 720 000 prevalent cases (5-year prevalence rate)^{1a}, 573 000 new cases and more than 200 000 deaths annually in 2020.^{1b}

Approx. 75% of all bladder cancer cases occur in men.¹ It has a high recurrence rate, with an average of 61% in year one and 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 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

¹ Globocan. a) 5-year prevalence / b) incidence/mortality by population. Available at: <https://gco.iarc.fr/today>, accessed [January 2022].

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. <https://www.cancer.org/cancer/bladder-cancer.html>

About Hexvix®/Cysview® (hexaminolevulinate HCl)

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 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, and New Zealand. Please refer to <https://photocure.com/partners/our-partners> for further information on our commercial partners.

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, www.hexvix.com, www.cysview.com

About KARL STORZ Endoscopy-America, Inc.

KARL STORZ Endoscopy-America, Inc., is an affiliate of KARL STORZ SE & Co. KG, an international leader for more than 75 years in advanced medical technology, providing surgical and procedural imaging, instrumentation, and enterprise-wide integration. Based in Tuttlingen, Germany, KARL STORZ

SE & Co. KG is a family-owned company that designs, engineers, manufactures, and markets all its products with an emphasis on visionary design, precision craftsmanship, and clinical effectiveness. For more information, call (800) 421-0837 or visit the company's website at www.karlstorz.com.

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