



THE
BLADDER CANCER
COMPANY

New Evidence: Positive Impact of Blue Light Cystoscopy on Recurrence in Bladder Cancer Presented at the Annual SUO Meeting

Press release – Oslo, Norway, December 5th, 2022: Photocure ASA, The Bladder Cancer Company, announces that new evidence was presented at the 22nd Annual Society of Urologic Oncology (SUO) Meeting demonstrating that Blue Light Cystoscopy (BLC[®]) decreases the risk and prolongs time to recurrence based on Real World Evidence from the U.S. multi-institutional Blue Light Cystoscopy with Cysview[®] Registry database.

This large, prospective, longitudinal, multisite registry collects data on NMIBC* patients who have undergone transurethral resection of bladder tumor (TURBT) using Blue Light as an adjunct to white light cystoscopy (WLC). The new data represent an interim analysis of the study, which is projected to enroll 4,400 patients in total. In this study, all registry patients analyzed (n=2055) received Blue Light. They were directly compared to a historical White-Light (WL)-only control group (n=261) of similar age, stage, grade, and clinical management (i.e., intravesical therapy).

Kaplan-Meier curves demonstrate recurrence-free survival (RFS) for BLC patients compared to a WL-only arm with a mean follow up of 27.4 months for BLC and 53 months for the historical WL control arm. The overall risk of recurrence was significantly lower following BLC compared to WLC alone (Hazard Ratio (HR) 0.33; 95% Confidence Interval (CI) 0.28-0.40, p-value=0<.0001). Authors indicate that the lower incidence of recurrence in the BLC arm were durable, as rates tracked over 5 years consistently out-performed WLC in the historical control group.

The data were presented at the Annual Meeting of the Society of Urologic Oncology meeting held November 30 – December 2, 2022, in San Diego, USA. The SUO is a congress led by internationally renowned urologic oncologists, medical oncologists, and scientists on topics of genitourinary medicine such as bladder, kidney, and prostate cancer. This year, Photocure has continued to partner with KARL STORZ with a joint exhibit featuring the new blue light SAPHIRA™ system, as well as information on flexible blue light.

"These real-world data from our U.S. Cysview Registry emphasize that better tumor detection and more complete resection using BLC can translate into more favorable long-term patient outcomes," said Geoff Coy Vice President and General Manager, North America. *"Interest in integrating BLC into the management of bladder cancer is high among practicing urologists,*

and many stopped by the exhibit at SUO to see the SAPHIRA demonstration unit on display and get hands-on experience with the upgraded system for TURBT procedures. SAPHIRA became commercially available in late September 2022, and we believe that the new system is helping to expand the use of BLC so that more patients diagnosed with bladder cancer have access to the benefits of enhanced cystoscopy.”

Read the abstract here: <http://suo-abstracts.secure-platform.com/a/gallery/rounds/15/details/2721>

*NMIBC: non-muscle-invasive bladder cancer

Note to editors

Hexvix[®]/Cysview[®] and BLC[®] are registered trademarks of Photocure ASA. Saphira[™] is a registered trademark of KARL STORZ Endoscopy.

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About Bladder Cancer

Bladder cancer ranks as the 8th most common cancer worldwide – the 5th most common in men – with 1 720 000 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 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 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: <http://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. <http://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, 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.

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

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