



THE
BLADDER CANCER
COMPANY

New BRAVO Study Publication Reinforces Clinical Benefits of BLC in Reducing Risk of Bladder Cancer Recurrence

Press Release – Oslo, Norway, March 14, 2025: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces the publication of the study “Oncologic Outcomes of Blue Light Cystoscopy in an Equal Access Setting: Results of the BRAVO study” in JU Open Plus this week. The research objective was to assess if blue light cystoscopy (BLC®) aided TURBT has an impact on the clinical outcomes of patients with NMIBC*. Results of the real-world evidence study show that BLC was associated with a statistically significant 38% reduction in risk of recurrence compared to white light cystoscopy (WLC) use alone in a predominantly high-risk NMIBC patient cohort. These results are in line with prior results from multiple randomized controlled clinical trials.

The BRAVO study (Bladder Cancer Recurrence Analysis in Veterans and Outcomes) is a propensity score matched, retrospective analysis evaluating clinical outcomes following BLC compared to WLC alone in patients from the Veterans Affairs Healthcare System.

626 patients were included in this study, 313 in each study arm (WLC versus BLC). Outcomes data for BRAVO was measured at a 3-year time point in a predominately high-risk patient population. Median age at diagnosis was 71 years. Median follow-up was 3.7 years.

Study results include:

- Risk of recurrence at 3-years was significantly reduced following BLC vs. WLC (HR, 0.62; 95% CI, 0.45-0.86; $p < 0.01$). The 38% reduction in the risk of recurrence is in line with prior results from multiple randomized controlled clinical trials. A positive trend for reduction in risk of progression was also observed (HR=0.71; 95% CI, 0.37-1.38; $p = 0.32$) at 3-years although not statistically significant due to a low number of patients progressing on the study.
- The study indicates that use of BLC can drive treatment decisions that lead to improved outcomes. Specifically highlighted in the study was that BLC patients were significantly more likely to receive intravesical BCG therapy (61% vs 43%; $p < 0.01$) or intravesical chemotherapy (48% vs 27%, $p < 0.01$). This data supports reasoning that using BLC enhances a clinician’s ability to decide on the appropriate bladder cancer therapy based on precision risk stratification and a more complete TURBT.

The Veterans’ Affairs (VA) Healthcare system accepts all U.S. Veterans, regardless of financial background, and retains its patients, allowing for high-quality data capture over a long-term follow-up period, therefore

serving as a robust real-world model for equal access.

"Bladder cancer detection plays an important role in preventing cancer recurrence and optimizing appropriate treatment pathways, as previous research has shown that WLC alone may not comprehensively detect all NMIBCs. In this propensity-score matched cohort study, we found that the use of BLC vs. WLC alone was associated with significantly decreased 38% risk of recurrence. Our results are in line with the recent Cochrane review of nearly 3,000 patients across 15 randomized trials, where the authors found that BLC may reduce the risk of bladder cancer recurrence by 34%. These data support current AUA/SUO guidelines recommending BLC usage in patients with NMIBC to increase detection and decrease recurrence", said Dr. Steven Williams, Professor and Chief of the Division of Urology, at the University of Texas-Medical Branch, and one of the study authors.

"The exciting long-term real-world results from the BRAVO study complement and confirm the generalizability of prior recurrence outcomes with BLC beyond the randomized controlled trial setting, reflecting a routine clinical practice patient population", said Anders Neijber, Chief Medical Officer of Photocure.

Read the full publication here:

http://journals.lww.com/juop/fulltext/2025/03000/oncologic_outcomes_of_blue_light_cystoscopy_in_an.3.aspx

An editorial to the publication can be found here:

http://journals.lww.com/juop/fulltext/2025/03000/editorial_comment_oncologic_outcomes_of_blue.4.aspx

*NMIBC: Non muscle-invasive bladder cancer

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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

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>

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.

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.

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