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BLADDER CANCER  
COMPANY

# Bladder Cancer: Long-Term Benefits of Blue Light Cystoscopy and Enhanced Detection with HD Technology Unveiled at AUA 2024

**Press Release – Oslo, Norway, May 7, 2024: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces its participation in the congress, and two abstract presentations at the AUA 2024: the American Urological Association Annual Congress 2024 was held May 3-6, 2024, in San Antonio, TX, USA. The results of the BRAVO study performed within the VA healthcare system showed significant decreases in the risk of recurrence and progression, as well as the potential for improved overall survival in patients who received a blue light cystoscopy (BLC®) compared to patients whose cystoscopy was only performed under white light. Another comparison of BLC with Hexvix®/Cysview® and white light cystoscopy (WLC), for the detection of bladder cancer using modern HD 4K equipment, was presented in an abstract from the multicenter phase III study of Hexvix in China, including new real world evidence data.**

**On Sunday, May 5<sup>th</sup>, Dr. Sanjay Das presented the study, "Use of Blue Light Cystoscopy Among Non-Muscle Invasive Bladder Cancer Patients and Outcomes in an Equal Access setting: A Propensity Score Matched Analysis."**

The study, known as BRAVO (**B**ladder Cancer **R**ecurrence **A**nalysis in **V**eterans and **O**utcomes), is a retrospective, propensity score matched analysis that evaluated oncologic outcomes following BLC compared to WLC alone in patients from the Veterans Affairs Healthcare System. The study addresses a lack of practical real-world data comparing the impact of BLC versus WLC, specifically for recurrence, progression, and survival. The results of this study confirm that BLC use is associated with positive and statistically significant impacts on these outcomes. 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.

626 patients were included in this study, 313 in each study arm (WLC versus BLC). Recurrence and progression data for BRAVO was measured at a 3-year time point. Overall survival follow-up was for 10 years.

Study results include:

- Risk of recurrence was significantly lower following BLC (HR 0.60, 95% CI 0.29-0.61) – 40% reduction in risk of recurrence. This confirms data from multiple RCT studies.
- Patients who underwent BLC had significantly reduced risk of progression (HR 0.51, 95% CI 0.36-0.99) compared to patients who underwent WLC.
- There was improved overall survival among BLC vs. WLC (HR 0.41, 95% CI 0.30-0.72)
- Additionally, in the equal-access setting of the VA Healthcare System, benefits of BLC were equitably shared between race/gender.

The Principal Investigator of the BRAVO Study, Dr. Steven Williams, commented: *"The results of the BRAVO study performed within the VA healthcare system showed significant decreases in the risk of recurrence and progression, as well as the potential for improved overall survival in patients who received a BLC compared to patients who received WLC only. These findings demonstrate the benefit of BL-enhanced cystoscopy as part of comprehensive care for NMIBC\* patients, especially as improved tumor visualization helps to appropriately make determination of intravesical therapy use, such as BCG. The results are encouraging and consistent with prior clinical trial long-term oncological outcomes. It supports the generalizability of prior clinical trial results in the real-world clinical practice setting. The demonstrated impact on overall survival warrants future studies to better understand the oncologic benefit of BLC in NMIBC"*

Read the abstract: <http://www.auajournals.org/doi/10.1097/01.JU.0001008712.53259.7d.05>

**On Monday, May 6th, a Poster presentation by Dr. Hailong Hu: Blue Light Cystoscopy versus White Light Cystoscopy for the Detection of Bladder Cancer using modern HD 4K equipment: An Analysis of Pivotal Trial and Real-World Data**

This pooled meta-analysis presented data from a randomized clinical trial and a supporting real-world evidence study conducted in China. Both studies enrolled patients with known or suspected bladder cancer. A total of 177 patients were enrolled, 128 patients underwent blue light cystoscopy (BLC) with Cysview (HAL) and were included in the full analysis set. Among patients diagnosed with Ta, T1, or CIS, 46 out of 109 patients (42.2%) had at least one lesion detected by BLC but not by white light cystoscopy (WLC) ( $p < 0.0001$ ). Fifteen patients had CIS of which 12 (80%) showed at least one additional CIS lesions found by BLC but not by WLC. The BLC detection rates for CIS, Ta, T1, and T2-T4 tumors were 95.2%, 100%, 98.3%, and 100%, respectively, while the WLC detection rates were 42.9%, 76.5%, 91.7%, and 100%, respectively.

This study confirms the superiority of HAL BLC over WLC in the detection of bladder cancer even if improved WLC using HD 4K equipment is utilized. In particular, additional high-risk difficult to see CIS lesions have been identified in 80% of CIS patients only by HAL BLC. The quality of resection is still a key cornerstone in the treatment of NMIBC of which BLC remains a crucial part despite the further development of WLC imaging.

Read the abstract: <http://www.auajournals.org/doi/10.1097/01.JU.0001009548.76580.ba.18>

Beyond this groundbreaking data on BLC/WLC comparison, Photocure provided attendees with hands-on experience in the blue light cystoscopy with Cysview procedure on its congress booth, that featured a Saphira HD equipment tower.

\*NMIBC: Non muscle-invasive bladder cancer

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## About Bladder Cancer

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

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

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.<sup>4</sup>

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

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

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

<sup>4</sup> 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](http://www.photocure.com), [www.hexvix.com](http://www.hexvix.com), [www.cysview.com](http://www.cysview.com)

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