



THE
BLADDER CANCER
COMPANY

New publication of Hexvix trial data from China: blue light cystoscopy with Hexvix significantly improves the detection of bladder cancer using modern HD equipment

Press release – Oslo, Norway, January 12th, 2026: Photocure announces the publication of the study "Hexaminolevulinate blue light cystoscopy improves bladder cancer detection in comparison to white light cystoscopy: a prospective, comparative, within-patient controlled multicenter phase III bridging study in China" in the *Frontiers of Urology* journal this week.

An abstract with data from this pivotal prospective randomized controlled multi-center Phase 3 trial was first presented at the Congress of the Société Internationale d'Urologie (SIU) in October 2023. Its main objective was to compare and show a significant improvement between Hexvix/Cysview® (hexaminolevulinate) blue light cystoscopy (BLC®) and white light cystoscopy (WLC) in the detection rate of bladder cancer, using Richard Wolf's modern state-of-the-art "System blue" high-definition cystoscopy equipment.

Of the 158 enrolled patients, 97 patients had non-muscle-invasive bladder cancer. Patients received intravesical Hexvix/Cysview and underwent WLC and high-definition BLC. The primary efficacy endpoint was the proportion of patients with histology-confirmed tumors (Ta, T1, or CIS) who had at least one such tumor detected during BLC, but not during WLC. Secondary endpoints included detection of CIS, lesion detection rates, false positive rate, and safety.

Key findings: Compared with WLC, the proportion of patients with additional bladder cancer lesions detected by BLC was 43.3% ($p < 0.0001$). The proportion of patients with CIS lesions detected by BLC and not by WLC was 9.6%. Detection rates for CIS, Ta, T1 and T2-T4 tumors were 94.7%, 100%, 98.2% and 100% for BLC and 42.1%, 76.1%, 91.2% and 100% for WLC, respectively.

The study authors conclude that in the setting of modern high-definition equipment, blue light cystoscopy with Hexvix/Cysview significantly improves the detection of bladder cancer and with favorable safety.

"The detection rates for CIS from this trial in a contemporary clinical setting using modern HD equipment are convincing, and in line with prior regulatory trials with BLC. The use of full HD cystoscopy equipment even seems to widen the tumor detection gap comparing white light

and blue light cystoscopy with Hexvix/Cysview. The difference in detection rates for CIS between BLC and WLC is 52.6% (18 out of 19 lesions, 94.7%, for BLC and 8 out of 19 lesions, 42.1%, for WLC). In 2025, we saw the evolution towards blue light cystoscopy use as best practice being recognized in the updates to several national urology guidelines. The role of enhanced cystoscopy for accurate staging and identifying CIS is increasing with the new emerging novel therapies in NMIBC," said Anders Neijber, Chief Medical Officer at Photocure.

Read the full publication here: <http://www.frontiersin.org/articles/10.3389/fruro.2025.1713128>

Note to editors:

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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 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 trademark in the U.S. and Canada, Hexvix is the trademark 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 HCI)

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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