Bladder Cancer presentations at AUA2025: Blue Light Cystoscopy improves risk stratification and informed decision making

Press Release – Oslo, Norway, April 29, 2025: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces four abstract presentations at the AUA 2025, highlighting the benefits of Blue Light Cystoscopy (BLC®), notably its impact on management of the disease, improved risk stratification and therefore the ability of the BLC procedure to help urologists and patients make well-informed decisions. The American Urological Association Annual Congress 2025 was held April 26-28, at the Venetian Convention & Expo Center in Las Vegas, NV, USA.

Three abstracts were presented from Photocure's U.S. Blue Light Cystoscopy with Cysview Registry, a large multicenter bladder cancer patient registry of real-world data, established by Photocure in 2014 and projected to enroll 4,400 patients. In addition, the study protocol of a randomized controlled non-inferiority trial comparing a multidisciplinary approach including PDD-guided primary TURBT to reduce the patients' burden of second resection including a total of 327 patients has been presented. This investigator-initiated trial is supported by Photocure.

The abstract sessions on Saturday, April 26:

"Upstaging and Risk Migration with BLC for NMIBC: Results from a prospective multicenter registry" by Alireza Ghoreifi, Duke University

The study looked at 2,854 NMIBC* patients from the US Blue Light Cystoscopy with Cysview Registry. A total of 201 (7%) patients had at least one malignant lesion detected exclusively by BLC while having a negative WLC. These lesions (335 in total) included carcinoma in-situ (CIS) (145; 43%), low-grade Ta (53; 16%), high-grade Ta (95; 28%), high-grade T1 (37; 11%), and high-grade T2 (5; 1%). As a result of BLC-enhanced detection, the rate of upgrading or upstaging to a more advanced tumor using BLC was 9.3%. The authors concluded that resulting changes in grade/stage could impact patient management, such as the appropriate administration of intravesical therapy, duration of therapy, and when to perform radical cystectomy. The results are expected to form the basis for further studies on how Blue Light Cystoscopy can support precision diagnostics and improve patient management in NMIBC.

Read the abstract:
http://www.auajournals.org/doi/abs/10.1097/01.JU.0001109740.05294.af.32

"Predicting Recurrence and Progression in Contemporary Patients with NMIBC Undergoing Blue Light Cystoscopy-Aided Transurethral Resection of Bladder Tumor" by Boris Gershman, Harvard University, Beth Israel Deaconess Medical Center

Although blue light cystoscopy (BLC) is recommended by clinical practice guidelines to reduce recurrence, predictive models for patients undergoing BLC are lacking. The authors developed predictive models for recurrence and progression in patients treated with BLC using 1109 patients. Median age at diagnosis was 71 years, and 198 (18%) patients were female. Tumor stage was Ta in 658 (60%), T1 in 241 (22%), and pure CIS in 210 (19%) patients. 759 (71%) patients had high-grade tumors, and 324 (29%) patients had multifocal disease. Median follow-up for relapse-free survival (RFS) and progression-free survival (PFS) was 18, and 24 months, respectively, during which time 360 recurrence and 79 progression events occurred. Results showed a greater number of tumors (unit HR 1.09), and recurrent tumor status (HR 1.32) were associated with increased risk of recurrence, while pure CIS (HR 0.69) and receipt of perioperative intravesical chemotherapy (HR 0.76) were associated with decreased risk of recurrence. In contrast, higher tumor stage (HR 3.88 for T1; HR 3.69 for T1+CIS) and lymphovascular invasion (HR 3.88) were associated with increased risks of progression. The impact of the data is that these models reflect contemporary treatment standards and can inform personalized, risk-adapted management of NMIBC.

Read the abstract:
http://www.auajournals.org/doi/abs/10.1097/01.JU.0001109740.05294.af.10

"Performance of the EORTC and CUETO Risk Prediction Models in Contemporary Patients Undergoing Transurethral Resection of Bladder Tumor with Blue Light Cystoscopy" by Boris Gershman, Harvard University, Beth Israel Deaconess Medical Center

In a companion study, the performance of the BLC recurrence/ progression model was compared against EORTC and CUETO, a pair of widely recognized risk tools for predicting recurrence and progression in non-muscle invasive bladder cancer (NMIBC). Out of total of 899 patients included from the BLC Registry, Ta was found in 658 (73%) patients and T1 in 241 (27%) patients, and concomitant CIS was present in 116 (13%) patients. Median follow-up for RFS and PFS was 18 and 24 months, respectively. The discrimination of the EORTC model was c=0.59 for RFS and c=0.67 for PFS, while for the CUETO model it was c=0.53 for RFS and c=0.72 for PFS. Thus, overall, in a contemporary cohort of patients undergoing BLC-TURBT, the EORTC and CUETO models demonstrated poor performance in predicting RFS and PFS.

Dr. Boris Gershman, principal author of these two abstracts commented: "Accurate prediction of recurrence and progression risk is essential for the management of non-muscle invasive bladder cancer. However, the established EORTC and CUETO risk models demonstrated poor performance forecasting these outcomes among contemporary patients receiving a TURBT with blue light cystoscopy. We therefore used the multi-institutional Blue Light Cystoscopy Registry to develop modern predictive models for recurrence and progression in patients treated with BLC. Such tools as these reflect contemporary treatment paradigms, and can inform the personalized, risk-adapted management of NMIBC."

"At AUA and EAU 2025 congresses we have seen important expert alignment these past weeks on the importance of early and accurate precision diagnosis in bladder cancer, and the role of blue light cystoscopy. Accurate diagnosis and risk stratification based on staging, grading impacts treatment decisions. It matters increasingly, the more advanced individualized treatment options a urologist is able to offer for the management of their patients' bladder cancer", said Anders Neijber, Photocure's Chief Medical Officer.

Read the abstract:
http://www.auajournals.org/doi/abs/10.1097/01.JU.0001109740.05294.af.18

On Monday, April 28, in "Clinical Trials in Progess":

"VI-RADS followed by Photodynamic Transurethral Resection of Non-muscle Invasive Bladder Cancer versus White-light Conventional and Second Resection: The CUT-LESS Randomized Trial" by Francesco del Guidici et al. from "Sapienza" University of Rome, Italy

The CUT-less trial aims to evaluate if second resection can be safely omitted in selected patients by combining cross-sectional imaging and PDD-guided primary TURB in order to reduce the burden of early repeated TURB for the patient.

This randomized controlled non-inferiority trial compares the short-term recurrence rates when combining preoperative staging using multiparametic magnetic resonance imaging (mpMRI) Vesical Imaging-Reporting and Data System (VI-RADS) and PDD-guided primary TURB vs. mpMRI Vi-RADs and white-light TURB only followed by second resection in patients which are candidates for second resection in NMIBC. This study will include a total of 327 patients. Secondary endpoints include comparative evaluation of mid- and long-term recurrence and progression rates, health-related quality of life, and health-economic cost-benefit analysis.

Read the abstract: http://www.auajournals.org/doi/10.1097/01.JU.0001110440.53375.7d

Beyond this groundbreaking volume and value of new data related to BLC, Photocure provided congress attendees with hands-on experience in the blue light cystoscopy with Cysview procedure on its booth, that featured a Fortec Mobile Equipment Demo of the Saphira HD equipment and rental option. In addition, other tech talks and expert sessions by equipment partners featured more aspects of blue light cystoscopy.

*NMIBC: Non-muscle invasive bladder cancer
**TURBT: trans-urethral resection of bladder tumors

Note to editors:

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.

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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