



THE
BLADDER CANCER
COMPANY

European Association of Urology (EAU) 2024 congress features new data on modern technology use in bladder cancer care

Press Release – Oslo, Norway, April 8, 2024: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces its participation in the congress, and two abstract presentations at the 2024 European Association of Urology congress (EAU) in Paris, France, highlighting the benefits of Blue Light Cystoscopy (BLC®) in Bladder Cancer management.

The EAU annual meeting is one of the largest international meetings in the urology calendar, showcasing the latest and most relevant clinical and scientific advancements in this area of patient care. This year's event was held on April 5-8, 2024, and attracted urologists from all over the world. Similar to last year, Photocure will make 2024 EAU bladder cancer session highlights available to healthcare professionals post event, by means of video interviews with the presenters of these sessions on the Photocure booth D26. This highly engaging and successful initiative is once again supported by two of the leading names in Bladder Cancer in Europe, Prof. M. Rouprêt, APHP, Sorbonne University Paris, France and Prof. P. Gontero, Division of Urology, University of Studies of Torino, Italy.

In addition to this educational activity, the EAU scientific program prominently features Photocure's Hexvix® product and/or the blue light cystoscopy procedure in which it is used. In particular, two notable abstract presentations were:

Outpatient laser coagulation of low-grade intermediate risk bladder tumor compared with TUR-BT, 12 months and long-term follow-up of a non-inferiority RCT (Abstract session 36 NMIBC: Benefits and harms of various treatment options, Sunday, 7 April, 17:15-18:45)

Treatment of recurrent low grade intermediate risk bladder tumor is burdensome for patients and health care system. The primary objective of this study was to evaluate 12 months recurrence-free survival after out-patient department photo coagulation of bladder tumors (PC-BT) is non-inferior to PDD-assisted TUR-BT in patients with recurrent Ta low grade bladder tumor. 154 patients were randomized for PC-BT and 146 for TUR-BT. 12 months follow-up data were available for 299 patients. 12 months recurrence-free survival was 42.2% after PC-BT and 44.1% after TUR-BT, the difference 1.9% (95%CI -9.3 to 13.2) in favor of TUR-BT. Regarding 12 months recurrence-free survival, the noninferiority criterion was met. Recurrence-free survival after OPD PC-BT is noninferior to TUR-BT at 12 months follow-up.

Incidence of long-term stage progression after PC-BT is noninferior to TUR-BT and very low after both treatment modalities. Treatment of recurrent Ta low grade intermediate risk bladder tumors in out-patient department with PC-BT appears to be a safe alternative to TUR-BT.

Read the abstract: <http://urosource.uroweb.org/resource-centres/EAU24/257251/abstract>

A prospective, comparative, within-patient controlled multicenter phase III study comparing blue light cystoscopy versus white light cystoscopy for the detection of bladder cancer using modern HD 4K equipment (Abstract session 46, Monday, 8 April, 12:30-14:00)

The study enrolled a total of 158 patients in a randomized controlled trial, and 114 patients underwent Hexvix blue light cystoscopy (BLC) and were in the full analysis set. Among patients diagnosed with Ta, T1, or CIS, 42 out of 97 patients (43.3%) had at least one lesion detected by BLC but not by white light cystoscopy (WLC) ($p < 0.0001$). Thirteen patients had CIS of which 11 (84.6%) showed additional CIS lesions. The BLC detection rates for PUNLMP, CIS, Ta, T1, and T2 ~ T4 tumors were NA, 94.7%, 100%, 98.2%, and 100%, respectively, while the WLC detection rates were NA, 42.1%, 76.1%, 91.2%, and 100%. 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 85% of all 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://urosource.uroweb.org/resource-centres/EAU24/257159/abstract>

"With the rapid advancement of technologies, emerging trends towards precision medicine and introduction of novel targeted agents which are transforming bladder cancer care, there is a renewed emphasis on the importance of the diagnostic process. Getting a correct and timely diagnosis is more important than ever. It's key to optimizing the subsequent care pathways and treatment decisions," said Anders Neijber, Chief Medical Officer of Photocure. *"These new results presented at EAU continue to emphasize the importance of using Blue Light Cystoscopy in the diagnosis of bladder cancer. BLC has been shown to clinically increase TURBT quality, more accurately stage disease, and enable better recurrence monitoring, supporting the long-term utility to help improve the lives of patients with bladder cancer."*

"Every year we see new data added to the body of evidence on Hexvix/blue light cystoscopy benefits, including with high-definition equipment. In Europe, our teams focus on helping their customers achieve the best possible image quality for BLC. We are convinced that when it comes to bladder tumor detection methods "seeing is believing", which is also our booth theme for this year's EAU. Many urologists try BLC, see what they see, and never look back", added Susanne Strauss, Vice President and General Manager Europe.

*TUR-BT/TURBT: trans-urethral resection of bladder tumors

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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.

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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