

New abstracts on the use of Blue Light Cystoscopy with Cysview presented at SUO

PRESS RELEASE – Oslo, Norway, 7 December, 2020: Photocure ASA (OSE:PHO) today announced new data and analyses presented at the 21st Annual Meeting of the Society of Urologic Oncology (SUO). Presentations discussed the use of Blue Light Cystoscopy (BLC™) with Cysview[®], in particular the positive impact on patient outcomes in the surveillance setting without a significant impact on the cost of care, as well as the benefits of identifying early recurrences in high-risk NMIBC patients undergoing BCG treatment.

The SUO meeting, held virtually this year, is led by internationally renowned urologic oncologists, medical oncologists, and scientists and attracts the interest of experts from all over the world.

"The use of BLC with Cysview continues to inspire the scientific community as much as ever for improving the care of patients diagnosed with bladder cancer. These new abstracts highlight the role of the procedure throughout patient care, especially focusing on the impact on patient management when used in surveillance. The Budget Impact Model supports the favorable cost-benefit of blue light procedures including in the office setting, while reaffirming its superiority in detection of non-muscle-invasive bladder cancer compared to white light alone. Both healthcare systems and patients clearly benefit from this standard of care procedure", said Dan Schneider, President and CEO of Photocure.

BLC with Cysview abstracts and posters have been prominently featured at the SUO meeting, including:

Budget Impact of Blue Light Cystoscopy in The Surveillance Setting

Stephen B. Williams, et al. The University of Texas Medical Branch

The Budget Impact Model was developed based on standard protocols for the treatment and surveillance of NMIBC. Inputs were based on a simulated facility with 50 newly diagnosed bladder cancer patients. Blue Light Cystoscopy (BLC) with Cysview was utilized for all surveillance cystoscopies. In the office setting, the additional use of flexible BLC for surveillance did not substantially impact cost and resulted in the identification of 9 recurrences over the course of two years that would otherwise be missed.

Link to the abstract

• Using BLC at the 3-Month Post-BCG Cystoscopy, Impact on Cancer Diagnosis, and Implications for Clinical Trial Design and Definition of BCG Response

Meera R. Chappidi, et al. University of California San Francisco

"We initiated this study because the utility of blue light cystoscopy (BLC) for surveillance in patients receiving BCG treatments is really not well understood. Thus, no recommendations exist in current guidelines. Beyond the obvious benefit of detecting recurrences that would otherwise be missed, we think that identifying early recurrences in patients receiving BCG can result in them being enrolled into clinical trials for BCG unresponsive disease in a timely manner", said Dr. Max Kates, Assistant Professor of Urology and Oncology, Co-Director, Bladder Cancer Multidisplinary Clinic, The James Buchanan Brady Urologic Institute of Johns Hopkins School of Medicine.

Based on findings from the Blue Light Cystoscopy (BLC) with Cysview Multi-institutional Registry, BLC-alone identified patients with recurrences after recent BCG treatment that would have been missed with White-light Cystoscopy (WLC) alone. This could be interpreted as WLC-alone incorrectly assessing inflated complete response rates in comparison to the more accurately measured results when BLC is added for surveillance (60% vs 55.3%). The implications of misidentified complete responses lead to inflated efficacy results, incorrect statistical findings and misguided conclusions. Future research is needed to clarify how BLC should be used for both entry into clinical trials and for surveillance while on trials.

Link to the abstract

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About Bladder Cancer

Bladder cancer ranks as the sixth most common cancer worldwide with 1 650 000 prevalent cases (5-year prevalence rate), 550 000 new cases and almost 200 000 deaths annually in 2018.¹

Approx. 75% of all bladder cancer cases occur in men. 1 It has a high recurrence rate with an average of 61% in year one and 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

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 (BLCTM). BLCTM with Hexvix[®] /Cysview[®] 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 the Nordic region and has strategic partnerships for the commercialization of Hexvix[®]/Cysview[®] in Europe, Canada, Australia and New Zealand. Please refer to https://bit.ly/2wzqSQQ 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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 $^{{\}small 1}\ Gobocan.\ Incidence/mortality by population.\ Available\ at: \\ \underline{http://globocan.iarc.fr/Pages/bar_pop_sel.aspx}$

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. https://www.cancer.org/cancer/bladder-cancer.html