

New publication shows that 91% of patients would recommend Blue Light Cystoscopy with Cysview®

Oslo, Norway, July 16, 2018: Photocure ASA (PHO:OSE) announced that the Patient Reported Outcomes (PRO) with Blue Light Cystoscopy (BLC™) with Cysview® Study was published online, in the prestigious British Journal of Urology, International:
<https://doi.org/10.1111/bju.14481>

The publication shows that patient anxiety levels decreased following flexible blue light cystoscopy with Cysview, and the vast majority of patients (94%) undergoing this procedure found it worthwhile and would do it again and recommend it to others (91%)¹. Receiving an instillation of the drug Cysview did not have a negative effect on PRO.

The PROMIS (Patient Reported Outcomes Measurement System) validated assessment tool was utilized to measure anxiety, pain and “was it worthwhile” in 262 patients. The assessment was part of the BLC with Cysview Phase 3 study that supported the February 2018 FDA approval for the use of BLC with Cysview in the surveillance setting with flexible scopes. This approval added to the indication for use with rigid cystoscopes in the operating room (OR).

“The reduction in anxiety, with the increased detection rates with BLC with Cysview and the fact that we are seeing patients actively seeking out BLC with Cysview should result in an improvement in patient outcomes in NMIBC, especially as Cysview is now used for ongoing surveillance of bladder cancer patients as well as in the OR,” says Ambaw Bellete, President, Photocure Inc. “We are grateful to the patients, their caregivers, investigators and the authors who had the foresight to include these measures in the Phase 3 study.”

As previously reported BLC with Cysview, using a flexible cystoscope, significantly increases the detection of overall Non-Muscle Invasive Bladder Cancer by 21% using BLC with Cysview. The increase with BLC is 35% for the detection of patients with Carcinoma in Situ (CIS)².

1. Daneshmand S, Patel S, Lotan Y, et al. Efficacy and Safety of Blue Light Flexible Cystoscopy with Hexaminolevulinate in the Surveillance of Bladder Cancer: A Phase III, Comparative, Multicenter Study. The Journal of urology 2018; 199:1158-65.

2. Patient-Reported Outcomes Measurement Information System. Anxiety: a brief guide to the PROMIS Anxiety instruments. In: Initiative NIOHNPR, ed. <https://www.assessmentcenter.net/documents/PROMIS%20Anxiety%20Scoring%20Manual.pdf>: NIH; 2015.

About Bladder Cancer Bladder cancer is the fifth most commonly diagnosed cancer in the US and is the fourth most common cancer found in men in the US^{1, 2, 3}. It is estimated that in 2018 there will be 81,190 new cases of bladder cancer will occur along with 17,240 deaths due to bladder cancer. Bladder cancer is one of the most expensive cancers to manage, accounting for approximately \$3.7 billion in direct costs each year.⁴

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.² NMIBC is still in the inner layer of cells. These cancers are the most common (75%) of all BC cases and include the subtypes Ta, carcinoma in situ (CIS) and T1 lesions. MIBC is when 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.²

About Hexvix®/Cysview®

Hexvix® is a drug that is taken-up selectively by cancer cells in the bladder making them glow bright pink during Blue Light Cystoscopy (BLC™). BLC™ with Hexvix® improves the detection of tumors and leads to more complete resection, less residual tumors and better management decisions.

Cysview® is the tradename in the US and Canada, Hexvix® is the tradename in all other markets. Photocure is commercializing Hexvix®/Cysview® directly in the US and the Nordic region, and has strategic partnerships for the commercialization of Hexvix®/Cysview® in Europe, Canada, Australia and New Zealand. Please refer to <http://bit.ly/PHO-Partnering> 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, which makes 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). The US headquarters for Photocure Inc., are in Princeton, New Jersey. For more information, please visit us at www.photocure.com, www.hexvix.com or <http://www.cysview.com>

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1. SEER Cancer Statistics Factsheets: Bladder Cancer. National Cancer Institute. Bethesda, MD. <http://seer.cancer.gov/statfacts/html/urinb.html>. Accessed April 2018.

2. Bladder Cancer. American Cancer Society <https://www.cancer.org/acs/groups/cid/documents/webcontent/003085-pdf.pdf>. Accessed April 2018.

3. Hall M, Chang S, Dalbagni G et al. Guideline for the Management of Nonmuscle Invasive Bladder Cancer (Stages Ta, T1, and Tis): 2007 Update. J Urol. 2007;178 (6):2314-2330.

4. Lotan Y, Kamat A M, et al. Key Concerns About the Current State of Bladder Cancer: Cancer Sept 2009; 4096-4103