



THE
BLADDER CANCER
COMPANY™

Photocure: First trial demonstrating reduced recurrence after flexible Blue Light Cystoscopy with Hexvix® in surveillance

Use of flexible Blue Light Cystoscopy at the first follow-up after TURBT* reduced the risk of tumor recurrence by 33% compared to white light alone. Randomized controlled multi-center study with 699 bladder cancer patients presented at Danish Urological Society meeting.

Oslo, Norway November 18, 2019, Photocure ASA (PHO:OSE), is pleased to announce that results from new studies with flexible Blue Light Cystoscopy (BLC™) with Hexvix were presented at the annual meeting of the Danish Urology Society on Saturday, November 16.

Results from a randomized controlled study in 699 patients from three urological departments in Denmark was presented. Patients were enrolled and randomized 1:1 to either flexible BLC with Hexvix or white light (WL) only cystoscopy at the time of first follow up after TURBT. Primary endpoint was tumor recurrence within eight months from the randomization. A total of 351 patients were allocated to the flexible BLC, and 348 to the control group). Throughout the following 8 months after randomization, only 117 patients in the BLC group had at least one tumor recurrence compared to 143 patients in the control group (P= 0.049). Odds ratio of 0.67 (P= 0.02, 95% CI: 0.48-0.95) correlates with a tumor reduction of 33% in favor of the BLC group.

The study authors (Ditte Drejer, Anne-Louise Moltke, Anna Munk Nielsen, Gitte Wrist Lam, Jørgen Bjerggaard Jensen) conclude that use of BLC in the first routine surveillance cystoscopy after TURBT for NMIBC** reduces subsequent risk of tumor recurrence compared to WL cystoscopy alone.

The study abstract can be found here (p. 48):

http://urologi.dk/sites/default/files/begivenheder/dus_bog_final_version_0.pdf

Experiences with flexible BLC with Hexvix in 119 patients at Lillebælt hospital in Denmark were also presented. Flexible BLC with Hexvix was introduced to replace procedures traditionally performed with rigid cystoscopes under general anesthesia; in control after intravesical treatment in high-risk patients, in patients with positive cytology and negative WL cystoscopy, in suspicious mucosal abnormalities under WL and in treatment of small recurrences.

The authors (Karen Spanggaard, Karsten Zieger, Gitte Kissow, Louise Fauerholt Øbro) conclude that flexible BLC and the possibility to biopsy in gel anesthesia was well tolerated and patient satisfaction was high. For most patients, BLC enabled treatment to be completed in the office. BLC was found to increase detection of urothelial disease and to add valuable information to WL cystoscopy and cytology.

The study abstract can be found here (p. 47):

http://urologi.dk/sites/default/files/begivenheder/dus_bog_final_version_0.pdf

* TURBT: trans-urethral resection of bladder tumors

** NMIBC: non-muscle invasive bladder cancer

About Bladder Cancer

Bladder cancer ranks as the ninth most common cancer worldwide with 430 000 new cases and more than 165 000 deaths annually. Approx. 75% of all bladder cancer cases occur in men¹. It has a high recurrence rate with an average of 61% in year one and 78% over five years². Bladder cancer has the highest lifetime treatment costs per patient of all cancers³.

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. 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 treat⁴.

About Hexvix®/Cysview® (hexaminolevulinate HCl)

Hexvix®/Cysview® is a drug that is selectively taken up by tumor cells in the bladder making them glow bright pink during Blue Light Cystoscopy (BLC™). BLC™ 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 US and Canada, Hexvix® is the tradename in all other markets. Photocure is commercializing Cysview®/Hexvix® 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 <https://bit.ly/2wzqSQQ> for further information on our commercial partners.

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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). For more information, please visit us at www.photocure.com, www.hexvix.com or www.cysview.com