



THE
BLADDER CANCER
COMPANY

New study demonstrates that tumor removal in the outpatient setting is as good as TURBT under general anesthesia

Press release – Oslo, Norway, September 20th, 2022: Photocure ASA, The Bladder Cancer Company, announces the publication of first results from the Laser III clinical study in the medical journal, European Urology. The study is part of a systematic program aimed at verifying the safe treatment of bladder tumors in the outpatient setting. Laser III results demonstrate the non-inferiority of outpatient laser-mediated destruction of bladder tumors in conjunction with blue light cystoscopy (BLC®) and Hexvix® versus inpatient BLC TURBT* under general anesthesia. Photocure has supported this program and the specific study since 2016.

Laser III is a prospective, randomized, non-inferiority trial conducted in the Capital Region of Denmark from 2016 to 2020 (NCT02886026). Patients with histologically verified Ta low-grade bladder tumor recurrence were enrolled. A total of 206 patients were randomized; 176 finished treatment and were available for follow-up as per protocol. The first results, now published in European Urology, evaluated 4-month non-inferiority of outpatient laser-mediated ablation of recurrent Ta tumors with flexible cystoscopes under local anesthesia, compared to TURBT under general anesthesia. Both the out-patient laser procedure and TURBT procedure were performed under BLC-guidance. Four-month recurrence-free survival was assessed as the primary endpoint with a predefined non-inferiority criterion of 15%. Secondary outcome measures were pain during the outpatient laser ablation, postoperative morbidity, postoperative complications, and patient's preference. The 12-month follow-up results are expected to be presented in a second paper.

Four-month recurrence-free survival was 8% higher after laser-ablation of the bladder tumor compared to TURBT, and the predefined noninferiority criterion was met. The study authors conclude that laser intervention in the outpatient setting is as good as TURBT with general anesthesia, and has less complications.

In addition, the paper also advocates the importance of enhanced cystoscopy to mediate this practice change. As recommended by the guidelines, enhanced cystoscopy should be used during surgical treatment of non-muscle invasive bladder cancer to improve detection and reduce recurrence.

"The study outcomes clearly demonstrate that for patients with small low grade stage Ta bladder tumors the procedure can be safely moved from the OR to the office, thereby reducing the burden for patients stemming from general anesthesia and cost related to hospital stays. Safety is the most important term here. Our team find that blue light cystoscopy with Hexvix in the OPD support the identification of small bladder tumors which therefore safely can be removed with laser before they become too large for outpatient treatment." said Dr. Gregers G Hermann, the Lead Investigator of this study and Consultant Urologist, MD, DM Sc, F.E.B.U., Dept. of Urology, Herlev/Gentofte hospital, Denmark.

"We expect to see more scientific studies investigating how some of the more intensive procedures like TURBTs can be reduced, avoided, or made more bearable for patients. In non-muscle-invasive bladder cancer especially, where most patients are over 55 years old, research into reducing patient burden is of great importance. We believe BLC with Hexvix/Cysview can help responsible researchers in these efforts by minimizing the concern of uncertainty when it comes to detecting the tumors," said Dan Schneider, President and CEO of Photocure.

Read the full publication here:

<https://www.sciencedirect.com/science/article/abs/pii/S0302283822025647>

(Clinicaltrials.gov <https://clinicaltrials.gov/ct2/show/NCT02886026>)

*TURBT: Transurethral resection of bladder tumor

Note to editors

Hexvix®/Cysview® and BLC® are registered trademarks of Photocure ASA.

This press release may contain product details and information which are not valid, or a product that is not accessible, in your country. Please be aware that Photocure does not take any responsibility for accessing such information, which may not comply with any legal process, regulation, registration, or usage in the country of your origin.

About Bladder Cancer

Bladder cancer ranks as the 8th most common cancer worldwide – the 5th most common in men – with 1 720 000 prevalent cases (5-year prevalence rate)^{1a}, 573 000 new cases and more than 200 000 deaths annually in 2020.^{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 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: <https://gco.iarc.fr/today>, accessed [January 2022].

² Babjuk M, et al. Eur Urol. 2019; 76(5): 639-657

³ Sievert KD et al. World J Urol 2009;27:295–300

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 <https://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

For further information, please contact:

Dan Schneider
President and CEO
Photocure ASA
Email: ds@photocure.com

Erik Dahl
CFO
Photocure ASA
Tel: +4745055000
Email: ed@photocure.com

David Moskowitz
Vice President, Investor Relations
Photocure ASA
Tel: +1 202 280 0888
Email: david.moskowitz@photocure.com

Media and IR enquiries:

Geir Bjørlo
Corporate Communications (Norway)
Tel: +47 91540000
Email: geir.bjorlo@corpcom.no