Photocure Welcomes FDA Proposal to Initiate the Reclassification of Blue Light Cystoscopy Systems from Class III to Class II

Oslo, Norway, August 14, 2026 – Photocure ASA (OSE: PHO), the Bladder Cancer Company, today announced that the U.S. Food and Drug Administration (FDA) has published a proposed order in the Federal Register to initiate the process of reclassifying cystoscopic systems intended as an aid for the detection of bladder cancer from Class III to Class II.

Importantly, FDA is initiating the proposed reclassification on its own initiative following its review of available scientific, clinical and post-market evidence. FDA states that there is sufficient information to establish special controls that, together with general controls, will provide reasonable assurance of the safety and effectiveness of these devices.

The proposed reclassification applies to cystoscopic systems intended for use with an approved optical imaging agent for photodynamic blue light cystoscopy (BLC®) as an adjunct to white light cystoscopy (WLC) for the detection of known or suspected bladder cancer, including carcinoma in situ, and for patients undergoing surveillance cystoscopy for bladder cancer.

"As indicated in the April 13 update on the regulatory classification for OAY equipment, this is a very important regulatory milestone for Photocure, physicians, and the bladder cancer community," said Dan Schneider, President and Chief Executive Officer of Photocure. *"FDA's decision to initiate the reclassification process on its own initiative reflects the Agency's conclusion that there is sufficient information to establish special controls for these devices and provide important regulatory recognition of the established safety and effectiveness of BLC. We believe the proposed framework is much better aligned with the technology's longstanding clinical use and regulatory experience and will serve as a tremendous catalyst for the U.S. business."*

A Significant Opportunity to Expand BLC Access in the United States

BLC with Cysview® is an established adjunct to WLC for the detection of non-muscle invasive bladder cancer (NMIBC). Cysview is an FDA-approved optical imaging agent that is instilled into the bladder prior to cystoscopy and enables malignant lesions to fluoresce under blue light, helping physicians visualize bladder cancer lesions that may not be visible under white light alone.

FDA's proposed reclassification follows its review of the regulatory and clinical history of these systems, including data from the original PMA, peer-reviewed literature, the FDA's 2009 Oncologic Drugs Advisory Committee meeting regarding Cysview, and available post-market safety information and subsequent submissions. FDA concluded that the available information supports establishing special controls for the device category and noted a lack of significant post-market safety signals.

When finalized, the proposed reclassification would move applicable cystoscopic systems from the current Class III premarket approval (PMA) pathway to Class II with special controls and premarket notification under the 510(k) pathway. FDA is not proposing to exempt these devices from 510(k) requirements but is proposing a new device class (Cystoscopic system intended as an aid for detection of bladder cancer).

"We welcome FDA's initiative to establish a regulatory framework that reflects the maturity of BLC and its established clinical use," said Dr. Anders Neijber, Chief Medical Officer of Photocure. *"We look forward to working with additional physicians, technology partners and other stakeholders to significantly expand access to BLC with Cysview for patients across the United States."*

Supporting Innovation and Expanded Access

Photocure believes that, when finalized, the reclassification will facilitate meaningful innovation and the development and introduction of additional standalone and add-on cystoscopic equipment platforms in the United States using BLC as the foundational technology.

Greater availability of compatible equipment will provide all hospitals and physicians with the opportunity to incorporate BLC into clinical practice and complement ongoing efforts to expand patient access, generate clinical and health-economic evidence, and support broader adoption of technology.

"The proposed transition to Class II will support greater innovation and significantly broaden the availability of BLC in the United States," said Geoff Coy, Vice President and General Manager North America at Photocure. *"Additional equipment platforms will give more hospitals and physicians the opportunity to incorporate BLC into their clinical practice and accelerate adoption of this established technology for bladder cancer patients, as we have seen with expanded access through our mobile solution collaboration with ForTec."*

The FDA's proposed reclassification remains subject to the applicable regulatory process, including a public comment period and FDA consideration of comments before any final order is issued. Until a final order becomes effective, the applicable cystoscopic systems remain subject to their current regulatory classification and requirements.

For more information, please contact:

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

Priyam Shah
Vice President Investor Relations
Tel: +17176815072
Email: priyam.shah@photocure.com

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

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 BLC® with 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.

The following safety information is solely included to comply with U.S. regulatory requirements: Important Risk & Safety Information for Cysview® (hexaminolevulinate HCl)

About Photocure ASA

Photocure is a commercial diagnostic company with global reach, committed to driving progress in uro-oncology precision diagnostics, delivering meaningful advances for patients with urological cancers. Our unique core technology has led to better health outcomes for patients worldwide. The company aims to provide an array of transformative solutions that help physicians with timely diagnostic information, to inform more personalized decisions on how best to manage each individual patient. Photocure is headquartered in Oslo, Norway and listed on the Oslo Stock Exchange (OSE: PHO). For more information, please visit www.photocure.com/news