



THE
BLADDER CANCER
COMPANY

Positive Results for Hexvix Phase III Clinical Trial in China Presented at the SIU 2023 Congress

Press Release – Oslo, Norway, October 12, 2023: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) has today unveiled the results of its Hexvix® (APL-1706) Phase III clinical trial in China. A presentation scheduled for today at the 43rd Congress of the Société Internationale d’Urologie (SIU), confirms that, in a Chinese population, Hexvix blue light cystoscopy (BLC®) outperformed white light cystoscopy (WLC) in the detection of bladder cancer, particularly in cases of carcinoma in situ (CIS), and exhibited good tolerability.

The highly statistically significant results corroborate the findings of Photocure’s own randomized controlled trials (RCTs) that demonstrate the clinical benefits of Hexvix BLC over WLC, specifically superior tumor detection and a favorable tolerability profile with no serious adverse events. Moreover, Asieris’ Phase III Hexvix trial is the first RCT conducted with high definition 4K blue light capital equipment.

"This randomized-controlled trial reinforces the benefits of BLC with Hexvix in tumor detection over WLC alone with clinically convincing and statistically significant results. This is on the backdrop of this Chinese trial being the first RCT conducted with 4K high definition (HD) blue light equipment, making it a valuable addition to the body of evidence already available on BLC with Hexvix. It confirms that BLC with Hexvix is additive to WL also with high quality HD imaging technology. We are pleased to see and acknowledge that our partners at Asieris are driving innovation to support unmet needs in bladder cancer", said Anders Neijber, Photocure’s Chief Medical Officer.

The trial results have been selected as a "late-breaking abstract" at the 43rd Congress of the Société Internationale d’Urologie (SIU) in Istanbul, Turkey, October 11-14. The clinical study data will be presented today, October 12, in the form of an Oral ePoster at 1:45pm local time.

The study is a prospective, self-controlled, multicenter Phase III study intended to evaluate the safety and detection benefits of blue light cystoscopy (BLC®) with Hexvix compared to white light cystoscopy (WLC) in the diagnosis of non-muscle invasive bladder cancer (NMIBC) in a Chinese population. The study included a total of 158 patients, of which 114 underwent BLC. Of the 97 patients diagnosed with NMIBC, a total of 42 patients (43.3%) had one or more additional lesions detected with Hexvix BLC compared to WLC ($p < 0.0001$). Among the 114 patients, 11.4% (13/114) had CIS lesions, and among these, 11 patients (84.6%, 11/13) had additional CIS lesions detected under Hexvix BLC that were not found under WLC. The

detection rates for PUNLMP, CIS, Ta, T1, and T2-T4 tumor lesions in the BLC group were NA, 94.7%, 100%, 98.2%, and 100%, respectively, while in the WLC group, they were NA, 42.1%, 76.1%, 91.2%, and 100%, respectively.

Read Asieris' full media release here: <http://asieris.com/asieris-unveiled-results-of-its-phase-iii-clinical-study-for-apl-1706-an-imaging-drug-for-diagnosis-or-surgery-of-bladder-cancer-at-the-siu-2023-congress/>

Asieris Pharmaceuticals is a global biopharma company specializing in discovering, developing and commercializing innovative drugs for the treatment of genitourinary tumors and other related diseases.

In January 2021, Asieris entered into a license agreement with Photocure ASA to obtain the exclusive registration and commercialization rights of Hexvix in mainland China and Taiwan.

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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 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 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 [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

4 Bladder Cancer. American Cancer Society. <http://www.cancer.org/cancer/bladder-cancer.html>

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 <http://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