



THE
BLADDER CANCER
COMPANY

Photocure Partner Asieris to present first results for its Hexvix Phase III clinical trial in China at the SIU 2023 Annual Meeting

Press Release – Oslo, Norway, October 7, 2023: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) has communicated its plan today to unveil the first results of its Hexvix® (APL-1706) Phase III clinical trial in China.

The pivotal clinical trial results have been selected as a “late-breaking abstract” for the 43rd Congress of the Société Internationale d’Urologie (SIU) in Istanbul, Turkey, this month. The clinical study results will be presented for the first time in the form of an Oral ePoster on Thursday, October 12, 2023, at 1:45pm local time.

The study is a prospective, self-controlled, multicenter Phase III study intended to confirm results from prior clinical trials regarding the safety and detection benefits of blue light cystoscopy (BLC®) 4K high definition with Hexvix compared to white light cystoscopy (WLC) in the diagnosis of non-muscle invasive bladder cancer (NMIBC) in a Chinese population. The primary endpoint in the trial is the rate of additional detection of one or more lesions including tumors with stages of carcinoma in situ (CIS), Ta, and T1 by APL-1706 BLC compared to WLC. As previously communicated, [the study reached its primary research endpoint](#) in August 2023 and the full results are expected to be submitted to Chinese regulators in support of a new drug application (NDA) in the coming months.

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.

Note to editors:

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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

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