



THE  
BLADDER CANCER  
COMPANY

## Photocure Partner Asieris announces 1<sup>st</sup> Patient enrolled in Hexvix Phase III trial in China

**Press Release – Oslo, Norway, November 4, 2022: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) has communicated today on the treatment of the first patient in the Hexvix® phase III bridging trial.**

The objective of the multicenter Phase III trial is to achieve regulatory approval of Hexvix in Mainland China for use in patients with bladder cancer, by investigating the detection rate and safety of Hexvix and blue light cystoscopy (BLC®) versus white light cystoscopy in patients with non-muscle invasive bladder cancer (NMIBC). The bridging trial is intended to confirm results from prior clinical trials in a Chinese population. The clinical trial protocol follows the protocols for registration studies in countries where Hexvix already has market authorization. This study will be led by Peking Union Medical College Hospital and the Chinese Academy of Medical Sciences.

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.

On December 26, 2021, Hexvix obtained initial clinical use in the Boao Lecheng International Medical Tourism Pilot Zone in Hainan Province, when the first patient received blue light cystoscopy with Hexvix at the Hainan General Hospital. The phase III clinical trial obtained approval from the National Medical Products Administration (NMPA) in the first quarter of 2022 and Hexvix was subsequently included in the real-world clinical data pilot program.

Read Asieris' full media release here: <http://asieris.com/hexvix-a-diagnostic-drug-for-bladder-cancer-of-asieris-completed-the-first-patient-dose-in-phase-iii-trial/>

The trial is registered here: <http://clinicaltrials.gov/ct2/show/NCT05600322>

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## **About Bladder Cancer**

Bladder cancer ranks as the 8<sup>th</sup> most common cancer worldwide – the 5<sup>th</sup> most common in men – with 1 720 000 prevalent cases (5-year prevalence rate)<sup>1a</sup>, 573 000 new cases and more than 200 000 deaths in 2020.<sup>1b</sup>

Approx. 75% of all bladder cancer cases occur in men.<sup>1</sup> It has a high recurrence rate with up to 61% in year one and up to 78% over five years.<sup>2</sup> Bladder cancer has the highest lifetime treatment costs per patient of all cancers.<sup>3</sup>

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.<sup>4</sup>

<sup>1</sup> Globocan. a) 5-year prevalence / b) incidence/mortality by population. Available at: <http://gco.iarc.fr/today>, accessed [January 2022].

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

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

<sup>4</sup> 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](http://www.photocure.com), [www.hexvix.com](http://www.hexvix.com), [www.cysview.com](http://www.cysview.com)

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