



THE  
BLADDER CANCER  
COMPANY

# Photocure Partner Asieris announces Approval to conduct a Phase III Clinical Trial for Hexvix in China

**Oslo, Norway, February 11, 2022: Photocure ASA (PHO: OSE), The Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) has obtained the Phase III clinical trial application (CTA) approval from the National Medical Products Administration (NMPA) of China for Hexvix®.**

The study is a prospective, multicenter bridging trial aimed to investigate the additional detection rate and safety of Hexvix® and blue light cystoscopy (BLC®) versus white light cystoscopy in Chinese patients with non-muscle invasive bladder cancer (NMIBC, tumor types CIS, Ta, T1). The study will be led by Peking Union Medical College Hospital, Chinese Academy of Medical Sciences. Professor Li Hanzhong, head of the Department of Surgery, Peking Union Medical College Hospital, will serve as the Principal Investigator to lead a team of top experts in the field of bladder cancer in China to carry out this study.

According to Frost & Sullivan, the number of new bladder cancer cases in China reached 86,000 in 2020, and is expected to rise to 101,000 in 2025, with a compound annual growth rate of 3.4% during the period. The total number of patients with bladder cancer in China was estimated to be higher than 600,000 in 2020. The use of BLC with Hexvix for the management of NMIBC is included in the global expert consensus guidelines.

In January 2021, Asieris Pharmaceuticals entered into a license agreement with Photocure, obtaining exclusive rights to register and commercialize Hexvix in mainland China and Taiwan. In December 2021, Hexvix was put into pilot use in the Boao Lecheng International Medical Tourism Pilot Zone in Hainan Province: [the first patient in China received blue light cystoscopy with Hexvix at Hainan General Hospital](#).

*"We are very glad that the phase III trial of Hexvix has been approved by the NMPA" said Dr. Yong Xue, Chief Medical Officer of Asieris. "We will accelerate the clinical trial process so that doctors and patients in China will have access to this breakthrough technology as early as possible."*

*"This clinical registration trial is a critical step toward giving bladder cancer patients access to Hexvix in China. Hexvix is a diagnostic agent that has been proven to improve the detection, and completeness of resection of tumors, and can be an important solution in the management of disease", said Anders Neijber, Vice President Global Medical Affairs and Clinical Development at Photocure.*

Read Asieris' full media release here: <https://asieris.com/asieris-announced-hexvix-a-drug-for-diagnosis-of-bladder-cancer%ef%bf%bc-has-obtained-the-ind-approval-from-the-nmpa-for-phase-%e2%85%b2-clinical-trial/>

## **Note to editors**

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## **About Bladder Cancer**

Bladder cancer ranks as the seventh most common cancer worldwide with 1 720 000 prevalent cases (5-year prevalence rate)<sup>1a</sup>, 573 000 new cases and more than 200 000 deaths annually 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 an average of 61% in year one and 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: <https://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. <https://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 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 and New Zealand. 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](http://www.photocure.com), [www.hexvix.com](http://www.hexvix.com), [www.cysview.com](http://www.cysview.com)

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