



THE  
BLADDER CANCER  
COMPANY

# Photocure Partner Asieris announces Marketing Approval by the National Medical Products Administration for Hexvix in China

**Oslo, Norway, November 5, 2024: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) has communicated today that its parent company Jiangsu Yahong Meditech Co., Ltd has received the marketing authorization for Hexvix® in China:**

The announcement states: Jiangsu Yahong Meditech Co., Ltd (hereinafter referred to as the "Company") has received the "Drug Registration Certificate" issued by the National Medical Products Administration, approving the marketing of the company's APL-1706 (Hexaminolevulinate Hydrochloride For Intravesical Solution). The relevant details of the drug are hereby announced as follows:

## 1. Basic Information of the Drug

Drug Name: Hexaminolevulinate Hydrochloride For Intravesical Solution

Trademark: 海克威®/Hexvix®

Drug Approval Number: 国口准字HJ20240119

Indications: Used for cystoscopy in patients with bladder cancer (including in situ cancer), including those with suspected or diagnosed bladder cancer based on previous cystoscopy results, or patients requiring cystoscopy during follow-up. This product is used in conjunction with blue light cystoscopy as an adjunct to white light cystoscopy.

## 2. Drug-related Information

The active ingredient of APL-1706 is Hexaminolevulinate (HAL). APL-1706, when used in conjunction with blue light cystoscopy, effectively increases the detection rate of bladder cancer, especially in situ carcinoma (CIS), leading to more complete surgical resections and thus reducing tumor recurrence rates. Before use, the patient empties their bladder, and the doctor instills APL-1706 dissolved in solution into the patient's bladder. APL-1706 forms photoactive intermediate products protoporphyrin IX (PpIX) and other photoactive porphyrins (PAPs) inside cells, which preferentially accumulate in tumor cells. Upon excitation by light at wavelengths of 360-450nm, the tumor tissue fluoresces bright red, with clear boundaries, while normal background tissues appear deep blue. This assists in the detection and surgery of

tumors under cystoscopy. The European Association of Urology (EAU), the American Urological Association (AUA), the National Comprehensive Cancer Network (NCCN), the National Institute for Health and Care Excellence (NICE) in the UK, the Chinese Urological Association (CUA) of the Chinese Medical Association, the Chinese Society of Clinical Oncology (CSCO), and the National Health Commission all recommend HAL as the preferred drug for fluorescence cystoscopy in their bladder cancer guidelines. They note that fluorescence cystoscopy can help detect tiny lesions in bladder cancer patients, especially CIS lesions.

### 3. Risk Warning

APL-1706 is a drug manufactured outside of China. After obtaining approval for marketing applications, activities such as overseas production, importation, and sales can proceed. However, its sales will be influenced by the progress of registration and market approval for blue light cystoscopes in China. Due to the nature of the pharmaceutical industry, the production and commercialization of drugs after obtaining marketing approval are subject to various factors such as policy environment, market needs and competition, which introduce a certain level of uncertainty. Investors are advised to make decisions cautiously, be mindful of investment risks, and take precautions accordingly.

This serves as the official announcement.

Board of Directors of the Company

November 5th, 2024

Read the stock exchange note (in Chinese)

here: [http://static.sse.com.cn/disclosure/listedinfo/announcement/c/new/2024-11-06/688176\\_20241106\\_ZJ33.pdf](http://static.sse.com.cn/disclosure/listedinfo/announcement/c/new/2024-11-06/688176_20241106_ZJ33.pdf)

-----

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. In December 2021, 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 clinical trial obtained approval from the NMPA in the first quarter of 2022 and Hexvix was subsequently included in the real-world clinical data pilot program.

Richard Wolf's System Blue, which has potential to be the first blue-light-enabled cystoscope approved in China, is currently under regulatory review by the NMPA. This Richard Wolf PDD device was used in the phase III clinical trial to develop Hexvix in China and the commercialization of Hexvix is dependent on the regulatory approval in the local market.

#### **Note to editors:**

All trademarks mentioned in this release are protected by law and are registered trademarks of Photocure ASA.

This press release may contain product details and information which are not valid, or a product is not accessible, in your country. Please be aware that Photocure does not take any responsibility for accessing such information which may not comply with any legal process, regulation, registration or usage in the country of your origin.

## 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 1 949 000 prevalent cases (5-year prevalence rate)<sup>1a</sup>, 614 000 new cases and more than 220 000 deaths in 2022.<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 [February 2024].

<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)

## For further information, please contact:

Dan Schneider  
President and CEO  
Photocure ASA  
Email: [ds@photocure.com](mailto:ds@photocure.com)

Erik Dahl  
CFO  
Photocure ASA  
Tel: +4745055000  
Email: [ed@photocure.com](mailto:ed@photocure.com)

David Moskowitz  
Vice President, Investor Relations  
Photocure ASA  
Tel: +1 202 280 0888

Email: [david.moskowitz@photocure.com](mailto:david.moskowitz@photocure.com)

Media and IR enquiries:

Geir Bjørlo  
Corporate Communications (Norway)  
Tel: +47 91540000  
Email: [geir.bjorlo@corpcom.no](mailto:geir.bjorlo@corpcom.no)