



THE
BLADDER CANCER
COMPANY

Photocure Partner Asieris confirms Hexvix Phase III clinical trial in China meets endpoint

Press Release – Oslo, Norway, August 11, 2023: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) has communicated today that the Hexvix® Phase III bridging trial in China has successfully met its primary research endpoint.

The objective of this multicenter Phase III trial is to support regulatory approval of Hexvix in Mainland China. The bridging trial is intended to confirm results from prior clinical trials regarding 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 clinical trial follows the same protocols for registration studies in countries where Hexvix already has market authorization.

A total of 158 patients were enrolled in this study. The completed statistical analysis results indicate that the study was successful and has achieved the primary research endpoint, which was defined as; the proportion of patients who have at least one tumor found by blue light but not by white light cystoscopy. The results of the study will be submitted to the Chinese National Medical Products Administration (NMPA) for a new drug application (NDA) in the coming months.

"The clinical data of Hexvix further confirms its outstanding clinical performance. We sincerely thank all the researchers and participants for their dedication and efforts in advancing this clinical research." said Dr. Linda Wu, Chief Development Officer of Asieris.

"This randomized clinical Phase III trial is the first being conducted with the Richard Wolf HD "System Blue" BLC equipment to support a regulatory registration. It will be exciting to see the impact of the improved image quality on outcomes and the incremental results of BLC in patients needing a transurethral resection of bladder tumors (TURBTs). We fully expect the Phase III trial in China to complement the robust randomized controlled clinical trials which support the international approvals and use of BLC and the benefits of BLC over WLC alone."; said Anders Neijber, Photocure's Chief Medical Officer.

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.

Read Asieris' full media release here: <http://asieris.com/asieris-announces-positive-phase-iii-bridging-trial-of-hexvix-a-diagnostic-drug-for-bladder-cancer/>

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

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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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