Photocure Partner Asieris announces completion of enrollment for Hexvix Phase III clinical trial in China

Press Release – Oslo, Norway, July 6, 2023: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) has communicated today that it has completed patient enrollment for the Hexvix® Phase III bridging trial.

The objective of the 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 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.

This study is being led by Peking Union Medical College Hospital and the Chinese Academy of Medical Sciences. Professor Li Hanzhong, head of the Department of Surgery at Peking Union Medical College Hospital, is serving as the Principal Investigator, leading a team of top experts in the field of bladder cancer in China to carry out this study. Asieris plans to file a new drug application with the National Medical Products Administration (NMPA) in the future, pending clinical trial progress and meaningful data.

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 phase III 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/hexvix-a-diagnostic-drug-for-bladder-cancer-of-asieris-has-completed-the-phase-iii-bridging-trial-enrollment/

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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