



THE
BLADDER CANCER
COMPANY

Photocure Partner Asieris announces New Drug Application acceptance for regulatory review of Hexvix in China

Press Release – Oslo, Norway, November 29, 2023: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) communicated today that the National Medical Products Administration (NMPA) accepted the new drug application (NDA) for Hexvix® (APL-1706) in China. Hexvix, a pharmaceutical product used in the detection of bladder cancer, was licensed to Asieris by Photocure in January 2021, for the registration and commercialization of Hexvix in mainland China and Taiwan.

Results of the Hexvix (APL-1706) Phase III clinical trial in China were presented at the 43rd Congress of the Société Internationale d'Urologie (SIU) last month, as a late-breaking abstract. The study confirmed that, in a Chinese patient population, Hexvix blue light cystoscopy (BLC®) outperformed white light cystoscopy (WLC) in the detection of bladder cancer, particularly in cases of carcinoma in situ (CIS), and exhibited good tolerability.

The highly statistically significant results corroborate the findings of Photocure's own randomized controlled trials (RCTs) that demonstrated the clinical benefits of Hexvix BLC over WLC, specifically superior tumor detection and a favorable tolerability profile with no serious adverse events. Moreover, Asieris' Phase III Hexvix trial is the first RCT that was conducted with high definition 4K blue light capital equipment.

Hexvix is currently the only approved optical imaging agent for diagnosing and surgical management of patients with bladder cancer worldwide. The combined use of Hexvix (APL-1706) and BLC for the management of non-muscle invasive bladder cancer (NMIBC) has been included in the global expert consensus guidelines and Chinese Urological Association Guideline. The drug has not yet been approved for market launch in China.

"We are glad to see our partners at Asieris driving the submission process with conviction and speed. The acceptance of the Hexvix submission by NMPA is the positive outcome of months of collaboration between the Asieris and Photocure teams", said Dan Schneider, President and CEO of Photocure. "We believe that BLC can make a difference which evident in the robust clinical data from many years of experience and the recent Chinese RCT data presented at SIU earlier this year. Both companies remain committed to bringing Blue Light Cystoscopy with Hexvix to more patients with bladder cancer and elevate the standard of care."

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.

Read Asieris' full media release here: <http://asieris.com/asieris-announces-nmpa-has-accepted-the-new-drug-application-for-apl-1706-an-imaging-drug-for-diagnosing-and-management-of-bladder-cancer/>

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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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