

# Photocure establishes Named Patient Program to provide access to Hexvix in South Africa

Press Release – Oslo, Norway, September 27, 2024: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that it entered into an agreement with Equity Pharmaceuticals PTY Limited, part of the Clinigen group, in September, to initiate a Named Patient Program (NPP) enabling bladder cancer patients in South Africa to receive blue light cystoscopy (BLC®) with Hexvix®.

Named Patient Programs (NPPs) provide access to medicines in response to requests by physicians on behalf of specific, or "named," patients when those medicines are not licensed or available in the patients' home country. Photocure's NPP with Equity Pharmaceuticals is designed to ensure that physicians can request Hexvix on behalf of individual patients residing in South Africa, with suspected or recurring bladder tumors. Hexvix blue light cystoscopy is indicated as adjunct to standard white light cystoscopy to contribute to the diagnosis and management of bladder cancer in patients with known or high suspicion of bladder cancer. Equity Pharmaceuticals will administer the NPP, and product sales are anticipated to begin in Q4 2024.

"Without this NPP, BLC with Hexvix would not otherwise be available to bladder cancer patients in South Africa. Photocure is committed to ensuring global access to Hexvix as part of its sustainability goals," said Dan Schneider, President and CEO of Photocure. "We see this program as a stepstone to trialing various ways in which Hexvix can be made available to patients and urologists in countries where BLC equipment is already accessible."

#### Note to editors:

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## **About Bladder Cancer**

Bladder cancer ranks as the  $8^{th}$  most common cancer worldwide – the  $5^{th}$  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. 1 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>

## About Hexvix®/Cysview® (hexaminolevulinate HCI)

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

### **About Clinigen**

Clinigen is a global, specialist pharmaceutical services company focused on providing ethical access to medicines. Its mission is to accelerate access to medicines for patients in every corner of the globe. The Group supports pharmaceutical and biotech companies across the medical product lifecycle, from clinical through to commercial and operates from sites in North America, Europe, Africa and the Asia Pacific. Clinigen has more than 1,000 employees across five continents in 15 countries and provides access in more than 130 countries every year.

For more information on Clinigen, please visit http://www.clinigengroup.com.

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<sup>&</sup>lt;sup>1</sup> Globocan. a) 5-year prevalence / b) incidence/mortality by population. Available at: http://gco.iarc.fr/today, accessed [February 2024].

<sup>&</sup>lt;sup>2</sup> Babjuk M, et al. Eur Urol. 2019; 76(5): 639-657

<sup>&</sup>lt;sup>3</sup> Sievert KD et al. World J Urol 2009;27:295–300

<sup>&</sup>lt;sup>4</sup> Bladder Cancer. American Cancer Society. http://www.cancer.org/cancer/bladder-cancer.html

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