

## **Strong recommendations for Blue Light Cystoscopy with Hexvix® in new French Guidelines**

Oslo, Norway, November, 21 2016: Photocure ASA (OSE:PHO) announced today that new 2016 French National Guidelines for the management of Bladder Cancer includes its Blue Light Cystoscopy (BLC) with Hexvix®. The new guidelines have been presented on November 17<sup>th</sup>, during Association of French Urologists (AFU) National Meeting, Paris, France published on line in Progres en urologie. Please click **here** for an abstract of the guidelines <http://bit.ly/2fj2yID>.

The French guidelines recommend BLC with Hexvix® for the first bladder cancer resection (TURBT) in essentially all patients and for consecutive TURBT's in the majority of patients. The recommendations are at an evidence level Grade B, demonstrating the strong clinical data supporting BLC with Hexvix®.

“The Association of French Urology National Bladder Cancer Guidelines for the management of patients with bladder cancer were last released in 2013. One of the biggest differences since the last guideline is that it now includes the situations BLC with Hexvix® can be used to reduce the risk of recurrence of NMIBC. The strong recommendation for use of blue light cystoscopy with Hexvix® should result in contributing to increasing the level of urological care for the management of patients with bladder cancer in France,” said M. Roupret, during his presentation on the guidelines at the AFU meeting, Professor of Urology Pitié-Salpêtrière - Hôpitaux de Paris University and one of the authors of the guidelines.

“The updated French National Guidelines recommending BLC with Hexvix® for such a wide range of patient types will result in BLC with Hexvix® being seen as standard of care. It is especially encouraging to see the strong recommendation for using BLC at the very critical first TURBT, which allows for the most correct staging and grading, which is crucial for the optimal follow-up and management of the patient. The recommendation for use in the first TURBT is also supported by Hexvix® cost effectiveness data developed for French conditions published in 2015<sup>1</sup>,” commented Kjetil Hestdal, MD, PhD, President and CEO, Photocure ASA.

In 2011, Photocure entered into a strategic collaboration with Ipsen to commercialize Hexvix®, its flagship product for the diagnosis and management of bladder cancer, worldwide except in the United States of America (USA) and the Nordic region. This technology represents a significant improvement for urologists and their patients. Ipsen is notably responsible for the commercialization of Hexvix® in France.

### **About Bladder Cancer**

Bladder cancer is the fifth most common cancer in men with more than 330 000 new cases annually and more than 130 000 die of the disease<sup>2</sup>. It has a high recurrence rate with an average of 61% in one year and 78% over five years, making the lifetime costs of managing bladder cancer one of the highest amongst all cancers. It is a costly, potentially progressive disease for which patients have to undergo multiple cystoscopies because of the high risk of recurrence. A recent paper on the economic burden of bladder cancer across the European Union estimates that bladder cancer cost the EU 4.9 billion Euro in 2012<sup>3</sup>. 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 is still in the inner layer of cells. These cancers are the most common (75%) of all bladder cancer cases and include the subtypes Ta, carcinoma in situ (CIS) and T1 lesions. MIBC is when 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.

### **About Hexvix®/Cysview®**

Hexvix®/Cysview® (hexaminolevulinate hydro-chloride) is an innovative breakthrough technology in the diagnosis and management of non-muscle-invasive bladder cancer. It is designed to selectively target malignant cells in the bladder and induce fluorescence during a cystoscopic procedure using a blue light enabled cystoscope. Using Hexvix®/Cysview® as an adjunct to standard white light cystoscopy enables the urologist to better detect and remove lesions, leading to a reduced risk of recurrence.

**Hexvix®** is the tradename in Europe, **Cysview®** in U.S. and Canada. Hexvix® is marketed and sold by Photocure in the Nordic countries and in the US with the trade name Cysview®. Photocure has a strategic partnership with Ipsen for the commercialization of Hexvix® in Europe, excluding the Nordic region. Please refer to <https://www.photocure.com/Partnering-with-Photocure/Our-partners> for further information on our commercial partners.

### **About Photocure ASA**

Photocure, headquartered in Oslo Norway, is a specialty pharmaceutical company and world leader in photodynamic technology. Based on our unique proprietary Photocure Technology® platform, Photocure develops and commercializes highly selective and effective solutions within disease areas with high unmet medical need, such as bladder cancer, HPV and precancerous cervical lesions, and skin conditions. Our aim is to provide solutions which can improve health outcomes for patients worldwide. Photocure is listed on the Oslo Stock Exchange (OSE: PHO). Information about Photocure is available at [www.photocure.com](http://www.photocure.com).

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## References

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2. Globocan. Incidence/mortality by population. Available at: [http://globocan.iarc.fr/Pages/bar\\_pop\\_sel.aspx](http://globocan.iarc.fr/Pages/bar_pop_sel.aspx) (accessed March 2015)
3. Leal et al, Eur Urol 2016; 69: 438-447