Photocure Partner Asieris announces positive international Phase III clinical trial results for Cevira and data presentations at the 2024 EUROGIN Congress and SGO Annual Meeting

Press Release – Oslo, Norway, March 18, 2024: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) has communicated today the Phase III clinical study results for its non-surgical treatment candidate for cervical high-grade squamous intraepithelial lesions (HSIL) Cevira® (APL-1702). The results were presented at two recent medical congresses and demonstrated highly statistically significant efficacy and a favorable safety profile for Cevira, with a significant clearance rate of high-risk HPV16 and/or HPV18 compared to placebo (p=0.0001).

Key data from the international multicenter Phase III trial were presented for the first time last week, in oral presentations at the 2024 European Research Organization on Genital Infection and Neoplasia (EUROGIN) Congress, March 13-16 in Stockholm, Sweden, and at the 2024 SGO Annual Meeting on Women's Cancer of the Society of Gynecologic Oncology, March 16-18 in San Diego, CA, USA.

- Cevira (APL-1702) is a pioneering photodynamic drug-device combination product used as a non-invasive therapy for treating cervical high-grade squamous intraepithelial lesions (HSIL). This study is a large prospective, randomized, double-blind, placebo-controlled international multicenter Phase III clinical trial designed to evaluate the efficacy and safety of APL-1702 for the treatment of cervical HSIL over 12 months. The primary endpoint of the study is the proportion of responders at 6 months after the initial treatment.

- Between November 2020 and July 2022, 402 eligible patients from various countries including China, Germany, and the Netherlands were randomized and enrolled in this study. In terms of the primary efficacy endpoint, the response rate in the APL-1702 group was significantly higher than that in the control group, with an increase of 89.4% (41.1% vs. 21.7%, p = 0.0001), which is considered a highly clinically relevant effect. Additionally, APL-1702 showed an improved clearance rate of high-risk HPV16 and/or HPV18, with a 103.9% increase in the APL-1702 group compared to the control group

(31.4% vs. 15.4%).

- The incidence of treatment-emergent adverse events (TEAEs) was comparable between the APL-1702 group and the control group, with the majority being mild and self-resolving without requiring intervention. The occurrence rates of treatment-related adverse events (TRAEs) and serious adverse events (SAEs) were low in both groups.

- The current progress involves ongoing communication with regulatory authorities in China and preparing for the submission of the new drug application for APL-1702. Additionally, active efforts are being made to advance development of the product outside of China.

"We are very pleased to see the strong results of this randomized controlled Phase III clinical trial in which Cevira (APL-1702) demonstrated clear benefit in patients with HSIL. Based on the results, treatment with Cevira has the potential to fill an unmet clinical need as an alternative to conventional surgical therapies for HSIL", said Anders Neijber, Photocure's Chief Medical Officer. *"At present, Photocure teams are supporting Asieris' to prepare the new drug application (NDA) for Cevira (APL-1702) in China, with the goal of bringing this innovative therapy to a larger number of patients as soon as possible."*

According to the press release, the main cause of cervical cancer is persistent infection with human papillomavirus (HPV), which leads to precancerous lesions of the cervix. Approximately 25% of individuals with HSIL may progress to invasive cervical cancer within 10 years. Read Asieris' full media release here: http://asieris.com/breakthrough-in-treatment-of-cervical-high-grade-squamous-intraepithelial-lesion-release-of-positive-results-from-multicenter-phase-iii-global-clinical-study/

Cevira (APL-1702) has potential to become a breakthrough photodynamic drug-device combination product that can offer patients the option of non-surgical treatment of high-grade precancerous lesions of the cervix. Photocure developed Cevira through Phase 1 and Phase 2 trials, and the global rights for development and commercialization were out-licensed to Asieris Meditech Co., Ltd in 2019. Asieris is a global biopharma company specializing in discovering, developing and commercializing innovative drugs for the treatment of genitourinary tumors and other related diseases.

Note to editors:

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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