Photocure Partner Asieris Unveils Cevira (APL-1702) Phase III Subgroup Analysis by Age Groups at the 2024 CSCO Annual Meeting

Press Release – Oslo, Norway, September 30, 2024: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) communicated that international multicenter Phase III clinical study data for its non-surgical treatment candidate Cevira® (APL-1702) for cervical High-Grade Squamous Intraepithelial Lesion (HSIL) has been published by the 27th Chinese Society of Clinical Oncology (CSCO) Annual Meeting as a poster, focusing on the analysis of different age subgroups regarding the six-month pathological regression rate and HPV clearance rate.

This Phase III clinical trial is a prospective, randomized, double blind, placebo controlled, multi-center clinical study, which has reached its primary efficacy endpoint and exhibited good safety.

Furthermore, the study results included the pathological regression rate (defined as the proportion of subjects with a pathological regression to CIN1 or normal tissue) at the 6th month across different age subgroups. Both the "≥20 and <30 years" subgroup and the "≥30 and <40 years" subgroup showed an increase of 15% to 20% in the pathological regression rate in the APL-1702 group compared to the placebo control group. No cervical cancer events were reported, suggesting a significant therapeutic potential of APL-1702 in the HSIL population aged 20 to 40 years.

Regarding HPV clearance rate, in the "≥20 and <30 years" age group, the APL-1702 group showed enhancements in the overall HPV clearance rate, HPV16-positive clearance rate, and HPV16/18-positive clearance rate compared to the placebo control group. The patients' number in the "<20 years" and "≥40 years" age groups were limited, thus the results in these age groups require a validation study with a larger sample size. Overall, APL-1702 not only facilitates the regression from HSIL to LSIL but also demonstrates the ability to induce clearance of high-risk HPV infections.

Read Asieris' full media release here: http://asieris.com/asieris-unveils-results-for-the-first-time-at-2024-csco-conference-the-subgroup-analysis-of-pathological-regression-rate-and-hpv-clearance-rate-at-6-months-in-different-age-groups-of-the-non-surgical/

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About Cevira®

Cevira® (APL-1702) is a photodynamic drug-device combination product in development. Based on the principles of photodynamic therapy, the Cevira product aims to use a photosensitizer in combination with light activation to produce a therapeutic effect as a non-surgical treatment of high-grade squamous intraepithelial lesions (HSIL) in patients aged 18 years and above, excluding carcinoma in situ. Photocure developed Cevira through Phase I and Phase II trials, and the global rights for development and commercialization were out-licensed to Asieris Meditech Co., Ltd in 2019. In November 2020 Asieris initiated the phase III clinical trial for APL-1702 (Cevira) which achieved its primary endpoint in September 2023, Clinical trial number: NCT04484415. The new drug application for APL-1702 was accepted by the National Medical Products Administration (NMPA) in May 2024.

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

About Asieris

Asieris Pharmaceuticals(688176.SH), founded in March 2010, is a global biopharma company specializing in discovering, developing and commercializing innovative drugs for the treatment of genitourinary tumors and other related diseases.

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