



THE
BLADDER CANCER
COMPANY

Photocure Partner Asieris announces that the First Non-Vaccine Investigational Product for Cervical HSIL has Achieved Its Primary Endpoint

Press Release – Oslo, Norway, September 20, 2023: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) has communicated today that the multinational Cevira® Phase III clinical trial has been completed and successfully met its primary endpoint. Cevira (APL-1702) is a photodynamic drug-device combination product in development for the non-surgical treatment of high-grade squamous intraepithelial lesions (HSIL), licensed to Asieris by Photocure.

The results of the study will be submitted to the Chinese National Medical Products Administration (NMPA) as part of a new drug application (NDA) in the coming months.

This study is a 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. It is led by Academy Member Dr. Jinghe Lang from Peking Union Medical College Hospital, Chinese Academy of Medical Sciences, and has enrolled 402 participants. The trial met its primary endpoint, together with a robust safety profile. Comprehensive data from this study will be presented at forthcoming academic conferences and published in scientific journals.

Dr. Linda Wu, Chief Development Officer of Asieris Pharmaceuticals, said *"This milestone marks a significant leap forward in the management of HSIL, with the potential to transform care in this domain. Moreover, tackling precancerous cervical conditions is pivotal for early prevention of cervical cancer and is an integral part of the three-tier cancer prevention system. Asieris Pharmaceuticals is committed to playing an active role in advancing China's Action Plan to Eliminate Cervical Cancer (2023-2030) and contributing to Healthy China 2030, aligning our efforts with the WHO's global strategy to accelerate the elimination of cervical cancer."*

"It is exciting to see that the Phase III clinical trial for Cevira has met its primary endpoint. There are many patients globally who can benefit from a non-surgical approach to treating high-grade squamous intraepithelial lesions (HSIL). Given the high unmet need and the importance of novel therapies to improve HSIL clinical outcomes, Photocure will continue to support Asieris, as our partner advances to the next stages of product development and

regulatory approval,"said Anders Neijber, Photocure's Chief Medical Officer.

According to the Global Cancer Statistics 2020, there were 604,127 new cases of cervical cancer in women, with 341,831 deaths worldwide, ranking it as the fourth most prevalent malignancy among females.¹ In China, cervical cancer ranks as the second most common malignancy among women.

The primary cause of cervical cancer is persistent HPV infection, leading to precancerous cervical lesions. Alarmingly, approximately 20 percent of individuals with HSIL may progress to invasive cervical cancer within a span of 10 years.² According to Frost & Sullivan, the number of HSIL patients is projected to reach 16.6 million globally and 2.2 million in China by 2030.

Read Asieris' full media release here: <http://asieris.com/the-first-non-vaccine-investigational-product-for-cervical-hsil-has-achieved-its-primary-endpoint/>

¹ Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2021;71(3):209-49.

² Expert Committee of Colposcopy and Cervical Pathology Branch (CSCCP) of Chinese Eugenics Association. Expert consensus on cervical cancer screening and abnormal management in China (II). *Chinese Journal of Obstetrics and Gynecology*, 2017, 18(3):286-288. (in Chinese)

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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), including all human papilloma virus (HPV) sub-types.

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), Clinical trial number: [NCT04484415](https://clinicaltrials.gov/ct2/show/study/NCT04484415).

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.

For further information, please contact:

Dan Schneider
President and CEO
Photocure ASA
Email: ds@photocure.com

Erik Dahl
CFO
Photocure ASA
Tel: +4745055000
Email: ed@photocure.com

David Moskowitz
Vice President, Investor Relations
Photocure ASA
Tel: +1 202 280 0888
Email: david.moskowitz@photocure.com

Media and IR enquiries:

Geir Bjørlo
Corporate Communications (Norway)
Tel: +47 91540000
Email: geir.bjorlo@corpcom.no