



THE
BLADDER CANCER
COMPANY

Photocure Partner Asieris announces New Drug Application acceptance for regulatory review of Cevira in China

Press Release – Oslo, Norway, May 12, 2024: Photocure ASA (OSE: PHO), the Bladder Cancer Company, announces that its partner Asieris Pharmaceuticals (SSE: 688176) communicated today that the National Medical Products Administration (NMPA) has accepted its new drug application (NDA) for the regulatory review of Cevira® (APL-1702, Hexaminolevulinate Hydrochloride Ointment Photodynamic Therapy System) for potential marketing authorization in China. 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.

"We are pleased that Cevira continues to advance toward market approval in China, as it can serve an important non-invasive option to treat pre-cervical cancer without the complications of surgical intervention," said Dan Schneider, President and CEO of Photocure. "Asieris continues to be a valued partner to Photocure, with solid execution on both programs that it has licensed from us. We look forward to further announcements on the regulatory progress of Cevira as well as Asieris' pending NDA for Hexvix in China."

The Asieris media release states: "APL-1702 is a first-in-class, non-surgical treatment for cervical HSIL with its efficacy proven in an international phase III trial. It heralds a potential paradigm shift in the treatment of precancerous cervical lesions, with the clinical focus moving from excision to long-term disease management. Emphasis lies in optimizing the delicate balance between treatment risks and benefits, striving to minimize or delay invasive procedures while effectively reversing the progression of the disease."

Read Asieris' full media release here: <http://asieris.com/asieris-announces-nmpa-acceptance-of-nda-for-apl-1702-a-non-surgical-therapy-for-treating-cervical-hsil/>

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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](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