Unique technology, unique track record

A world leader in photodynamic technology, Photocure develops and commercialises dermatology products and cancer treatments, based on its proprietary Photocure Technology® platform. The Norwegian-based company recently announced the approval of the Special Protocol Agreement (SPA) from the US FDA on the design of the Phase 3 clinical registration programme for Cevira, which it has in development for the treatment of high grade pre-cancerous lesions of the cervix. This is good news, says Kathleen P. Deardorff, Pharm. D., Chief Operating Officer at Photocure, who also explains why Cevira® is a breakthrough technology.

Photocure was founded by the Norwegian Radium Hospital in 1997. Today, the company, headquartered in Oslo, Norway, has over 60 highly skilled employees and operates in Norway, Sweden, Denmark, Finland and the United States.

Ms. Deardorff explains that Photocure's proprietary photodynamic technology delivers several benefits: "It's a very targeted treatment, in other words very selective to the disease tissue, so that the healthy tissues are preserved. This in turn results in very few side effects."

What also makes Photocure stand out is that it has a successful track record not just in drug development, but also in commercialisation. Metvix, a dermatology product which it sold to Galderma in 2009, was the first PDT product developed and commercialised by Photocure, and it generated a strong return on the company's investment. Hexvix®, an optical imaging agent used for detection of bladder cancer, is successfully commercialised by Photocure itself in the US and across the Nordic region. The company meanwhile continues to advance its pipeline of compounds, which notably includes Cevira.

Cevira is a breakthrough technology, says Ms. Deardorff. "In the past, photodynamic technology overall had an inherent commercial barrier. The light source and photo sensitizer were two different systems. We for the first time have fully integrated the drug and light device into one small, convenient, integrated product." Patients with pre-cancerous cervical lesions currently lack optimal treatment options. Patients with higher risk for developing cancer are referred to an invasive, surgical procedure (conisation) that may lead to impaired function of the cervix and increased risk of premature birth. While patients with less serious lesions, "watchful-waiting" is currently the preferred management, meaning that patients are referred to tedious gynaecological examinations which have limited detection capability.

Following completion of Cevira's phase 2b programme, the FDA agreed that Photocure met requirements. Prior to initiating phase 3 registration protocols, the company submitted for an SPA. "The SPA mechanism allows for much reduced risk of going into phase 3," says Ms. Deardorff. "The FDA are basically saying that if the protocols are conducted in this fashion and meet the specified endpoints, then that should be adequate to gain approval. It's not a guarantee, of course, but does significantly reduce the risk."

Photocure's strategy is to find a strategic partner for continued development and commercialisation of Cevira, preferably in the women's healthcare space.

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