# sagentia innovation

# Cevira

### Photocure



# Breakthrough light activated drug-device investigated for treatment of HPV and cervical pre-cancer

Cevira is a non-surgical, tissue-preserving therapeutic procedure that addresses the treatment of Human Papilloma Virus (HPV). HPV is estimated to be the most common sexually transmitted infection in the United States and can result in an increased risk of developing cervical cancer. Current procedures include laser therapy, surgical conisation, LEEP excision or cryotherapy and these can damage healthy tissue and cause long term health issues including post-surgical infections, reduced fertility, and an impeded ability to carry a child full-term.

#### **Expertise**

- · Technology landscaping
- Device concepts
- Design engineering
- Optical design
- Electronic design
- · Materials selection
- Design for assembly
- LED technology

#### Domain knowledge

- Patient journey
- LED therapy
- Clinical trials
- Medical device regulation and approval process
- Cost reduction for better patient outcomes



#### Our client asked:

Photocure, a Norwegian specialty pharmaceutical company focused in dermatology and cancer, asked Sagentia Innovation to partner with them to develop a device that would work in combination with Photocure's pharmaceutical as a non-surgical alternative to treat HPV and cervical pre-cancer. The goal of the project was to more effectively remove HPV infection and treat precursors of cervical cancer.

# The project story:

Working in partnership with Photocure, we started with a technology assessment exercise to map out the most viable technology for the device and generated device concepts. A key part of the project was carrying out user research to look at form and fit – ensuring these were right early in the project meant a smoother transition to the subsequent detailed engineering phase and resulted in the best end product.

Following proof of concept, including clinical tests, and detailed design engineering, including optical design, electronic design, materials selection and design for assembly, Sagentia Innovation has on behalf of and in collaboration with Photocure developed a design suitable for clinical trials. Sagentia Innovation continues to work with Photocure on the manufacture for clinical trials and ongoing development.

## Contact us

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### Results: deliverables and outcomes

- Cevira is a drug-device combination procedure which delivers a targeted light-activated treatment that destroys tissue infected by HPV and treat precancerous lesions on the cervix, without damaging healthy tissue
- Cevira was accepted for use in a Phase II clinical trial by the US FDA. The trials included 240+ patients in multiple centres across the United States and Europe
- This is the first therapeutic treatment that uses advanced LED technology in a self-powered, disposable device which can be deployed inside a body cavity. The device contains a LED light source that in combination with a medicinal product initiates a photochemical reaction in exposed tissue
- The fully integrated single-use device is easily administered by a trained gynaecologist or colposcopist and is then left in place on the cervix for up to 24 hours, during which time the patient is able to leave the hospital and continue with her daily activities, before removing and disposing of the device herself
- By combining recent advances in LED technology with expertise in optics, electronics and medical device development, Sagentia Innovation and Photocure have developed a viable alternative to invasive treatments that is expected to improve patient health outcomes and help reduce costs for the healthcare system

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