Photocure

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

Human Papilloma Virus (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. Photocure, a Norwegian specialty pharmaceutical company focused in dermatology and cancer, asked Sagentia 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.

Approach

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 has on behalf of and in collaboration with Photocure developed a design suitable for clinical trials. Sagentia continues to work with Photocure on the manufacture for clinical trials and ongoing development.

Results

Cevira is a drug-device combination procedure which delivers a targeted light-activated treatment that is intended to be used to destroy 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 trial, started in 2011 including 240 patients, is taking place in multiple centres across the United States and Europe and will be reported at the end of 2012. The clinical trial is investigating this advanced form of photodynamic therapy in patients with mild cervical abnormalities and precancer as an alternative to current surgical procedures.

Unlike previous applications of photodynamic therapy for the treatment of cancer, 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 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 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.

“This is the first ever non-surgical treatment for HPV and precancerous lesions of the cervix to be successfully developed. If this sophisticated and breakthrough device is accepted, it will make way for a new era in cervical cancer treatment that will not only minimise patient risk and suffering but could also help reduce the burden of HPV on healthcare systems.”

Dr. Peter Hillemanns  Professor and Chairman at the Department of Obstetrics and Gynaecology of Medical University Hannover, and principal investigator for the trial