

## National Cancer Institute supports next-generation Austrian HPV vaccine

October 30 2014

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Credit: Fotolia

The National Cancer Institute in the USA is supporting the new vaccine developed at the MedUni Vienna against the human papillomavirus (HPV) with at least US\$ 3.5 million. This is a major success for the developers and means that the foundations can now be laid for the clinical trials needed for licensing as a vaccine.

The National Cancer Institute (NCI) of the US National Institutes of Health (NIH) is supporting further clinical development of a new, improved, next-generation HPV vaccine. The vaccine was developed by a team led by Reinhard Kirnbauer from the Division of

Immunodermatology at the MedUni Vienna in collaboration with Christina Schellenbacher and support from the Austrian Science Fund (FWF) and Vienna Science and Technology Fund (WWTF). The new vaccine had already demonstrated its excellent efficacy in a pre-clinical study in 2013.

Kirnbauer's research team has now successfully competed in a hard-fought selection process for the support of the NCI's PREVENT Cancer Program, which amounts to at least US\$ 3.5 million. Over the next year and a half, the new vaccine will be produced under cGMP ("current good manufacturing practice") conditions in the USA. In a second stage, the vaccine will be prepared for licensing as an IND (Investigational New Drug) by the FDA (Food and Drug Administration, USA). This is essential to initiate early phase human clinical trials already being planned.

## **Seal of quality for tremendous importance of the new HPV vaccine**

The funding from the NCI is a crucial step towards clinical trials, however it also highlights the tremendous importance of the newly developed vaccine. Says Kirnbauer: "Our new HPV vaccine is one of the rare cases in which the NCI grants this "seal of quality" to a research group outside the USA by facilitating the production of a vaccine for [clinical trials](#)."

## **Significantly improved effectiveness compared to HPV vaccines available to date**

In laboratory studies and in pre-clinical tests, this vaccine has already demonstrated significantly broader effectiveness against a range of high and low-risk types of HPV compared to the vaccines that have been

available so far. For the first time, the new vaccine also promises protection against HPV types that cause various types of skin warts. These are not only unsightly, but they can also cause serious problems for immunosuppressed patients. Unlike the vaccines that have been available so far - Kirnbauer is also an inventor of the HPV16 VLP contained in these - that contain two or four antigens, the new vaccine has just one antigen (HPV16 RG1-VLP) and is therefore technically easier and more economical to manufacture. After the hepatitis B vaccine, the HPV vaccine is so far only the second effective cancer [vaccine](#).

## **Service: Manufacturing of medications under cGMP conditions**

Good Manufacturing Practice (GMP) means guidelines designed to ensure the quality of production sequences and environments, especially those involved in the manufacture of medicines and active ingredients. The term "good manufacturing practice" was introduced in 1962 by the US Food and Drug Administration (FDA) through the "current Good Manufacturing Practice (cGMP) initiative."

Provided by Medical University of Vienna

Citation: National Cancer Institute supports next-generation Austrian HPV vaccine (2014, October 30) retrieved 25 April 2024 from <https://medicalxpress.com/news/2014-10-national-cancer-next-generation-austrian-hpv.html>

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