Abstract

The vision of therapeutic cancer vaccines is to effectively target and destroy all tumor cells while leaving healthy cells unharmed. Current strategies are based on target structures on the tumors (i.e., antigens found commonly in a high proportion of cancer patients). Recently, several clinical trials showed good safety and promising signs of clinical activity of such cancer vaccines. The Glioma Actively Personalized Vaccine Consortium (GAPVAC) is taking cancer vaccines to the next level by assessing the individuality of each patient’s disease to utilize the full antigenic potential of immunotherapy. GAPVAC’s goal is to deliver to patients a novel class of medicine: actively personalized vaccines (APVACS), which are actively tailored to the tumor characteristics of each individual patients.

Mission

GAPVAC will be among the first clinical projects in the direction of fully active personalized medicine, where patients will be treated based on specific characteristics of their individual disease. For design and manufacturing of APVACS, very sophisticated methods have to be applied with the following long-
term objectives: (a) extend patients’ lives in a meaningful fashion and (b) increase the proportion of patients responding to therapy.

Because a fully personalized approach has never been tested in clinical development before, the primary objectives for the GAPVAC Phase I clinical trial are as follows:

### Consortium History

- **July 2014:** Second GAPVAC Annual Meeting
- **August 2014:** European Commission approved project progress
- **October 2014:** GAPVAC to advance novel class of fully personalized therapeutic cancer vaccines into clinical trials for brain cancer
- **November 2014:** GAPVAC clinical trial highlighted in *The Washington Post*

### Structure & Governance

GAPVAC is led by two highly innovative biotechnology companies based in Europe: immatics biotechnologies GmbH (coordinator) and BioNTech AG (vice coordinator) that are dedicated to applying the best science for the benefit of patients. Ten academic centers in Europe and the U.S. will recruit patients and collect scientific data for the GAPVAC clinical trial. Academic centers are located in Barcelona (Spain), Copenhagen (Denmark), Geneva (Switzerland), Haifa (Israel), Heidelberg (Germany), Leiden (The Netherlands), Pittsburgh (U.S.), Southampton (UK), and Tuebingen (Germany). The personalized vaccine will be manufactured at BCN Peptides (Barcelona, Spain) and the University of Tuebingen (Tuebingen, Germany). Moreover, results will be disseminated by the Association for Cancer Immunotherapy (CIMT), which will also contribute to the scientific analysis.

GAPVAC will focus on the development of a fully and actively personalized vaccination approach, in which patients will be treated based on specific characteristics of their individual disease. To assess this, GAPVAC will be divided into a section for preclinical/translational development and a subsequent clinical Phase I trial to assess safety, feasibility, and immunogenicity of APVACs. The project plan will cover 11 Work Packages (WPs): WPs 1-4 cover the preclinical phase of the project, WPs 5-9 cover the clinical trial, and WPs 10-11 cover management of GAPVAC and the dissemination plan.
Financing

GAPVAC is a collaborative project supported by the European Commission’s Seventh Framework Programme 2012 and specifically addresses the call “HEALTH-2012-INNOVATION-1-1.2-1: Development of technologies with a view to patient group stratification for personalised medicine applications.”

The aim of this topic is to support research and development and/or proof of principle of technologies for application in the area of personalized medicine (i.e., tailored medical interventions that are more effective and have fewer undesirable adverse effects in specifically defined patient groups). These technologies should be of use for research, screening, diagnostics, and/or guidance of therapeutic interventions. The projects must include quality control aspects for data generated and where appropriate use statistical tools. Potential end users should actively be included in the project, at least for proof-of-principle projects.

GAPVAC is supported with €6 million from the European Union. The total project has a volume of €7.9 million. The project started in November 2012 and is planned to be completed in January 2017.

Patent Engagement

Within the GAPVAC project, patients presenting with fully resectable, suspected glioblastoma will be treated by a vaccine, especially designed and manufactured according to characteristics of his/her individual disease. First, the surgically resected tumor will be analyzed. During this time, patients will start their standard therapy (chemoradiotherapy). As soon as the personalized vaccine is available, patients will be repeatedly vaccinated on top of the standard therapy.

Several European hospitals and one hospital in the U.S. will take care of patients recruited to the clinical trial and will treat patients with standard therapy and the novel APVAC approach.

Links/Social Media Feed

Homepage  http://gapvac.eu/
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