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# EU join hands to develop personalized cancer vaccines

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**Singapore:** Europe has established Glioma Actively Personalized Vaccine Consortium, (GAPVAC), a project designed to create, manufacture and develop actively personalized vaccines (APVACs) to fight cancer. The consortium aims to conduct multi-national clinical trial, to start by 2014, treating glioblastoma patients with fully personalized therapeutic vaccines.

GAPVAC is the first EU-funded initiative aimed at clinically developing biomarker-guided actively personalized vaccines (APVACs) to treat cancer patients. The consortium consists of 14 organizations from the biotech industry and academia with cutting-edge expertise in cancer vaccine development. The consortium will be led by immatics biotechnologies GmbH (Coordinator) and BioNTech AG (Vice Coordinator). Both companies are located in Germany and are dedicated to a biomarker-guided approach to fight cancer.

The latest technologies, including next-generation sequencing (NGS), high-sensitivity mass spectrometry and innovative immunomonitoring approaches, will be combined to generate an optimal therapy for the individual patient.
GAPVAC will address the high unmet medical need in glioblastoma, an aggressive form of brain cancer with poor prognosis, where the limited treatments available today have minimal effect on overall survival. The project aims to show that APVACs are well tolerated and induce a strong and specific immune response against cancer. Furthermore, the partners will demonstrate that this novel personalized approach is feasible.

immatics and BioNTech will jointly take this actively personalized approach to immunotherapy into clinical development. At the

core of the GAPVAC project is a phase 1 clinical trial which will enroll up to 30 newly diagnosed glioblastoma patients and is expected to start in 2014. Glioblastoma patients will be repetitively immunized with a vaccine specifically prepared for them. This actively personalized vaccine will be administered in addition to standard chemotherapy after surgery and initial radiochemotherapy are completed. The clinical trial will be led by chief investigator Prof. Dr. Wolfgang Wick, University of Heidelberg, and co-led by Prof. Dr. Pierre-Yves Dietrich, University of Geneva, both internationally recognized experts in the treatment and immunology of brain cancer.

BioNTech will add proprietary glioblastoma-expressed tumor-associated antigens to the peptide warehouse. BioNTech and immatics will use their next-generation sequencing (NGS) and mass spectrometry expertises, respectively, to identify immunogenic tumor mutations and generate a blueprint for the personalized vaccine that will include patient-specific tumor mutated peptides. For the first time, BioNTech has demonstrated that the integrated use of NGS for genome-wide mutation identification (the "mutanome") followed by mutation-targeting vaccination is feasible and leads to tumor control in pre-clinical models. immatics will use its unique antigen discovery engine XPRESIDENT to generate a warehouse of tumor-associated peptides (TUMAPs) from which the most suitable for each patient are selected based on transcriptomic and peptidomic analysis to create the first of two APVACs applied to the patient.

The APVAC "on-demand" manufacturing will be performed by the GMP-unit at the Department of Immunology (led by Prof. Hans-Georg Rammensee), University of Tuebingen, Germany. The complex peptide warehouse will be manufactured by BCN Peptides in Spain, an enterprise focused on peptide synthesis for clinical use. In addition, ten academic partners from Europe and the US have joined the consortium to apply the APVACs to their patients as well as contributing to the project with their own research. These will be: Eberhard Karls University Tuebingen (Germany), Beatson West of Scotland Cancer Centre (Scotland), Universities Hospital Geneva (Switzerland), Universities Hospital Heidelberg (Germany), Herlev Hospital/ Rigshospitalet (Denmark), Leiden University Medical Centre (The Netherlands), University of Pittsburgh Cancer Institute (US), University Southampton (UK), Technion (Israel), Vall d'Hebron University Hospital (Spain).

The clinical trial will be accompanied by an extensive biomarker program led by the Association of Cancer Immunotherapy (CIMT), a non-profit organization dedicated to the advancement of cancer vaccines, and immatics to confirm the mechanism-of-action and to identify biomarker signature candidates predicting which patients are most likely to benefit from treatment with APVACs. CIMT will also act as the dissemination platform and will contribute to the biomarker program and regulatory approach through its working parties.

Prof. Dr. Ugur Sahin, Chief Executive Officer of BioNTech AG and Vice Coordinator of the GAPVAC consortium, noted: "The GAPVAC consortium is dedicated to take patient care to the next level. This novel approach marks a fundamental paradigm shift in the therapeutic management of cancer patients since the approach is suited to provide a truly individualized and targeted drug development at unprecedented speed. In fact, currently we are able to provide ready to administer personalized drugs within 3 months whereas average time from target-to-hit to first in human testing is about 5.5 years."