

## **EU-funded consortium led by BioNTech and Immatics announces completion of regular study treatment in the GAPVAC-101 trial**

### **Study is assessing fully personalized therapeutic cancer vaccines for patients with brain cancer**

**Mainz/Tuebingen, Germany, 24<sup>th</sup> March 2017:** BioNTech AG and Immatics Biotechnologies GmbH announce today the completion of regular study treatment in the GAPVAC-101 clinical trial. The phase 1/2 trial assesses for the first time therapeutic cancer vaccines designed and manufactured for each glioblastoma patient individually based on the specific characteristics of their tumor and immune system.

The clinical trial is being 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.

The **Glioma Actively Personalized Vaccine Consortium (GAPVAC)** is the first EU-funded initiative aimed at clinically developing biomarker-guided **actively personalized vaccines (APVACs)** to treat patients with glioblastoma. The GAPVAC consortium includes 13 organizations in Europe and the United States and is led by Immatics Biotechnologies GmbH (coordinator) and BioNTech AG (vice coordinator).

Until completion of patient recruitment in July 2016, the phase 1/2 clinical trial has recruited 16 newly diagnosed glioblastoma patients. To-date the trial has shown that the consortium's highly personalized, complex multi-peptide APVACs can be designed and manufactured within the European regulatory environment and within acceptable time lines for physicians and patients. Moreover, APVACs are well tolerated and show an acceptable safety profile. Results from the trial including immune data analysis are expected in the second half of 2017. Some patients are still continuing APVAC vaccinations beyond the last regular study visit under the discretion of their treating physicians to fully exploit the potential benefit from the APVACs specifically tailored to their disease.

Prof. Dr. Wolfgang Wick, Chair of the Neurology Clinic at the University of Heidelberg, said: "I'm excited to announce that we have completed regular study treatment in the GAPVAC-101 trial. I am pleased to report that we have successfully managed the highly complex process of sample collection, analysis, vaccine design and manufacturing. This enabled us to offer personalized APVACs to all patients in the study, showing that a truly personalized vaccine approach is feasible. We believe that it provides a blueprint for future trials in personalized medicine. Congratulations to the Consortium for the achievements."

Prof. Dr. Ugur Sahin, Chief Executive Officer of BioNTech AG and Vice Coordinator of the GAPVAC consortium, said: "The GAPVAC consortium used individual tumor mutations in glioblastoma as targets for cancer immunotherapy. With the GAPVAC clinical trial, the consortium proved that this approach of truly individualized treatments is feasible and furthermore promising to significantly extend the treatment options for cancer patients."

**Notes to editors:****About the project**

GAPVAC was launched in 2013 and designed to create, manufacture and develop actively personalized vaccines (APVACs) tailored to the individual characteristics of the patient's tumor and immune system. It is based on combining latest state-of-the-art technologies, including next-generation sequencing (NGS), high-sensitivity mass spectrometry and innovative immunomonitoring approaches to generate an optimal therapy for the individual patient.

The consortium is supported by a €6 million grant from the European Union Framework 7 (EU FP7) program.

**About the partners**

BioNTech used its next-generation sequencing (NGS) expertise to identify immunogenic tumor mutations and to generate a blueprint for the personalized vaccine that included patient-specific tumor mutated peptides. Previously, BioNTech has demonstrated that the integrated use of NGS for mutation identification followed by mutation-targeting vaccination is feasible and led to tumor control in pre-clinical models.

Immatics used its unique antigen discovery engine XPRESIDENT® to generate a warehouse of tumor-associated peptides (TUMAPs) from which the most suitable for each patient were selected based on transcriptomic and peptidomic analysis to create the first of two APVACs applied to the patient.

The APVAC "on-demand" manufacturing was performed by the GMP unit at the Department of Immunology (led by Prof. Dr. Hans-Georg Rammensee and Prof. Dr. Stefan Stevanovic), University of Tuebingen. The peptide warehouse was manufactured by BCN Peptides in Spain, an enterprise focused on peptide synthesis for clinical use. In addition, nine academic partners from Europe and the US are part of the consortium to apply the APVACs to their patients as well as contributing to the project with their own research. These are: Eberhard Karls University Tuebingen (Germany), University Hospital Geneva (Switzerland), University Hospital Heidelberg (Germany), Herlev Hospital/ Rigshospitalet (Denmark), Leiden University Medical Centre (The Netherlands), University of California San Francisco (United States), University Southampton (UK), Technion (Israel) and Vall d'Hebron University Hospital (Spain).

The clinical trial is being 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 also acts as the dissemination platform and contributes to the biomarker program and regulatory approach through its working parties.

For more information about GAPVAC, visit the consortium website [www.gapvac.eu](http://www.gapvac.eu).

**About BioNTech AG**

BioNTech is Europe's largest privately held biopharmaceutical company pioneering the development of individualized therapies for cancer and other diseases. The company combines all building blocks for individualized immunotherapy under one roof – from diagnostics and drug development to manufacturing. Its cutting-edge technologies range from individualized mRNA-based medicines through innovative chimeric antigen receptors and T-cell receptor-based products to novel checkpoint immunomodulators. BioNTech's approach is validated by five top-tier corporate partnerships with Genentech, Genmab, Eli Lilly and Company, Sanofi and Bayer Animal Health. Founded in 2008, BioNTech's shareholders include the MIG Fonds, Salvia and the Strüngmann Family Office, with the Strüngmann Family Office as the majority shareholder. More information about BioNTech is available at [www.biontech.de](http://www.biontech.de).

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