



***Nature* Publication Reports Favorable Clinical Trial Results of BioNTech's Individualized Cancer Vaccine IVAC® MUTANOME**

- First-ever clinical study demonstrates personalized RNA-based vaccine using mutant neo-epitopes as antigens activates immune system against individual mutations and exerts anti-cancer activity -

Mainz, Germany, July 5, 2017 – BioNTech AG, a fully-integrated biotechnology company pioneering individualized cancer immunotherapy, today announced Phase I trial results demonstrating its IVAC® MUTANOME, an individualized RNA vaccine based on patient-specific mutations, induces strong immunogenicity as well as promising anti-tumor activity in high-risk patients with late-stage melanoma. Additionally, in this early trial, a majority of patients showed prolonged progression-free survival in comparison to historical controls. The first-in-human study applied a process covering the comprehensive identification of individual mutations from routine tumor biopsies to next generation sequencing, the computational prediction of potential neo-epitopes as vaccine targets, and the design and manufacturing of an RNA vaccine encoding multiple neo-epitopes unique for each patient. The data, published today online in *Nature*, were obtained from research conducted in collaboration with clinical partners and the translational research institute, TRON.

In the first-in-human application of a personalized RNA-based vaccine approach, 13 patients with melanoma were treated. The vaccine boosted immunity against multiple tumor antigens in all patients, and infiltration of vaccine-induced T-cells into tumors was observed in two patients. Eight of the 13 patients remained tumor-free at 23 months; five patients had tumor relapses before starting neo-epitope vaccination. Two of these patients experienced objective responses after neo-epitope vaccination and one patient had a complete response after sequential administration of neo-epitope vaccination and anti-PD-1 therapy.

“Each patient developed immune responses against multiple vaccine targets. This suggests that in principle, it may be possible to train a patient’s immune system to help fight their cancer across a wide array of tumor types,” said Ugur Sahin, Founder and CEO of BioNTech. “The clinical findings with objective responses in some patients are very encouraging. While our study documents early findings, additional trials are needed to further evaluate safety, clinical efficacy over time and across larger patient cohorts.”

BioNTech’s IVAC® MUTANOME platform is being developed in collaboration with Genentech, a member of the Roche Group. The companies are currently working with health authorities to validate, standardize, and apply the entire process globally and in the United States.

The study is entitled “[A personalized neo-epitope RNA vaccine mobilizes potent, poly-specific T-cell immunity against cancer.](#)”

The current issue of *Nature* also carries a [commentary](#) highlighting the study findings.

Collaborators of BioNTech and TRON were the University Medical Center of the Johannes Gutenberg University, Mainz, Germany; EUFETS GmbH, Idar-Oberstein, Germany; Medical University of Vienna, Vienna, Austria; German Cancer Research Center (DKFZ), Heidelberg, Germany; University Medical Center Mannheim/Heidelberg University, Mannheim, Germany; and Ci3 Cluster for Individualized Immunointervention e.V., Mainz, Germany.

For more information, please contact:

General Inquiries:

BioNTech AG

Regina Jehle

Tel: +49 6131 9084 1273

Email: Regina.Jehle@biontech.de

US Media & Investors:

ICR Healthcare

James Heins / Stephanie Carrington

Tel: +1 203 682 8251

Tel: +1 646 277 1282

Email: James.Heins@icrinc.com

Email: Stephanie.Carrington@icrinc.com

International Media & Investor Inquiries:

akampion

Dr. Ludger Wess / Ines-Regina Buth

Tel: +49 40 8816 5964

Tel: +49 30 2363 2768

Email: info@akampion.com

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 financial 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.

About TRON - Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg-Universität Mainz gGmbH

TRON, or Translational Oncology at the University Medical Center of the Johannes Gutenberg University, is located in Mainz, Germany and is a not-for-profit biopharmaceutical research organization. TRON integrates cutting-edge technologies and interdisciplinary expertise in genomics and next-generation sequencing, bioinformatics and biostatistics, immunology, immunotherapy, and molecular biology to accelerate transfer of novel concepts and innovation from basic research into clinical applications. With its core competencies of highly specialized technologies and methods, TRON supports academic institutions, biotech companies and the pharmaceutical industry in the development of innovative products.

More information about TRON can be found at www.tron-mainz.de.