



Breakthrough Development in Cancer Immunology Published in Nature

Potential for truly personalized treatment of any cancer

Mainz, Germany, 22 April 2015: [BioNTech AG](#), a fully integrated biotechnology company developing truly personalized cancer [immunotherapies](#), announces the publication of a scientific article on therapeutic immune responses to cancer in the internationally renowned scientific journal Nature. The paper shows an important scientific foundation for the clinical development of truly personalized yet broadly applicable cancer treatment for any patient. This publication represents results from an interdisciplinary collaboration between scientific and clinical teams at TRON, La Jolla Institute for Allergy and Immunology and BioNTech AG to elucidate novel cancer immunotherapy principles, translate these into individually tailored mRNA cancer vaccines and progress clinical development to provide new treatment options for cancer patients. The paper can be found here:

<http://dx.doi.org/10.1038/nature14426>

The article entitled "[Mutant MHC II epitopes drive therapeutic immune responses to cancer](#)" describes a novel immunological principle relevant to cancer immunotherapy and how this translates into patient specific mRNA cancer vaccines targeting multiple mutations. Ugur Sahin, co-founder and CEO of BioNTech and colleagues, identified tumor-specific mutations capable of inducing immune responses in mouse models of skin, breast and colon cancer, and showed that a large fraction of these mutations can be recognized by immune cells called CD4⁺ T cells. The study shows that the proportion of mutations recognized by immune cells is at least ten times higher than previously reported. The finding is extremely important as immune recognition of tumor-specific mutations has been previously shown to be required for clinically successful cancer immunotherapy.

Ugur Sahin, CEO of BioNTech, said: *"This novel insight indicates that most human cancers may be eligible for successful cancer immunotherapy. However, every patient's tumor possesses a unique set of mutations that must first be identified, which means that targeted vaccine approaches need to be individually tailored. Our aim is to make truly personalized cancer immunotherapies affordable and broadly available."*

The paper outlines a novel technology solution that uses this insight for truly personalized medicine. It describes a blueprint for personalized yet broadly applicable cancer treatment. This involves computer assisted design of a tailored cancer vaccine using a patient's cancer genome data – the "mutanome". It also confirms that "just in time" production of a patient specific mRNA cancer vaccine, that importantly targets multiple mutations, is feasible.

These discoveries have already been implemented by BioNTech in a first-in-concept clinical trial (NCT02035956) in melanoma, using its fully integrated and operational process from sequencing each patient's tumor to delivery of that patient's individualized cancer vaccine. This approach can either be



used as a standalone treatment or combined to improve the clinical success of checkpoint blockade treatment. Further studies are being planned. BioNTech owns all commercial rights for the exclusive exploitation of the entire concept.

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Notes to editors

About BioNTech AG

BioNTech AG (Biopharmaceutical New Technologies) is a leading, immunotherapy company that researches, develops and manufactures innovative, truly personalized, highly potent and well-tolerated immunotherapies for cancer and other diseases. Its focus is on pioneering, disruptive technologies ranging from individualized mRNA based medicines through highly innovative Chimeric Antigen Receptors /T-cell Receptor-based products and antibody checkpoint immunomodulators. Established by clinicians and scientists, BioNTech is striving to develop uniquely individualized therapies through its pioneering research programs. Its clinical programs are supported by an internal molecular diagnostics-based unit that is preparing to launch its first in-vitro diagnostic for breast cancer. Founded in late 2008, BioNTech is privately held and raised the largest initial financing round in the history of the European biopharmaceutical sector. 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 limited liability company (LLC) based at that prestigious university. It is a biopharmaceutical research organization that pursues new diagnostics and drugs for the treatment of cancer and other severe diseases with high medical need. TRON was founded specifically to accelerate knowledge transfer 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.

About La Jolla Institute for Allergy and Immunology

The La Jolla Institute for Allergy and Immunology is dedicated to understanding the intricacies and power of the immune system so that we may apply that knowledge to promote human health and prevent a wide range of diseases. Since its founding in 1988 as an independent, nonprofit research organization, the Institute has made numerous advances leading toward its goal: life without disease®. Get to know more about La Jolla at www.liai.org