CIMT
Cancer Immunotherapy

NEWS RELEASE

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New blueprint outlines a regulatory framework for novel "actively personalized" vaccines ("APVACs")

CIMT-RRG proposal published in Nature Biotechnology enables the clinical development of personalized therapies

Mainz, Germany, Oct. 10, 2013 – The Regulatory Research Group of the Association for Cancer Immunotherapy (CIMT-RRG) has published a blueprint for the development of actively personalized vaccines (APVACs). The proposal, published in the October issue of *Nature Biotechnology*, outlines how APVACs may be pursued within the existing regulatory framework of the European Union (EU).

Personalization of cancer treatment has been proposed as a solution to increase the efficacy of novel therapies to treat cancer. The availability of whole genome sequencing enables therapeutic concepts that actively use whole genome data to design tailored vaccines that target the unique genomic alterations found in an individual patient's tumor. Such "actively personalized vaccines (APVACs)" have not yet been tested in patients. APVAC concepts that lead to unique medicines for every individual patient change the paradigm of how drugs are developed and clinically tested and thus pose a series of regulatory challenges. The CIMT Regulatory Research Group has analyzed the existing EU regulatory framework and has come to the conclusion that APVACs may be pursued within established principles. A meeting with the Innovation Task Force of the European Medicines Agency (EMA) confirmed the possible path for the development of APVACs as proposed by the CIMT Regulatory Research Group.

"Our publication shows that the specific concepts already in use for cellular therapies may be applicable for individualized therapies," says Ulrich Kalinke, director of TWINCORE and corresponding author of the paper in Nature Biotechnology. "Even if challenges remain, the first hurdle for clinical testing of this new class of therapies is cleared."

"This is a milestone publication for the clinical translation of the APVAC concept," says Cedrik Britten (Ribological GmbH, Mainz), one of the authors of the paper. "Where there had previously not been any regulatory guidance for such actively personalized therapies, we have been able to describe a possible path that will facilitate human testing of individually tailored medicine."

"I am very pleased that this was an international effort as it would not have been possible for single individuals or institutions," says Harpreet Singh (Immatics Biotechnologies, Tübingen), also a co-author

of the paper. “The results of the Regulatory Research Group pave the way for the future of personalized immunotherapies from which researchers and developers worldwide will benefit.”

Reference:

Britten CM, Singh-Jasuja H, Flamion B, Hoos A, Huber C, Kallen K-J, Khleif SN, Kreiter S, Nielsen M, Rammensee H-G, Sahin U, Hinz T, Kalinke U (2013): The regulatory landscape for actively personalized cancer immunotherapies, *Nature Biotechnology 31 (10)*, 880-882. doi 10.1038/nbt.2708.

About the Regulatory Research Group (RRG) of the Association for Cancer Immunotherapy (CIMT

Founded in 2008, the CIMT Regulatory Research Group is an independent group of experts from academia and pharmaceutical industry focusing on regulatory aspects of drug development. The group aims to identify the regulatory challenges posed by emerging immunotherapies, to discuss and develop new regulatory concepts that enable the clinical testing of innovative immunotherapies, and to facilitate discussion between all groups relevant for the translation of scientific knowledge from bench top bedside

About the Association for Cancer Immunotherapy (CIMT)

The Association for Cancer Immunotherapy (CIMT) is an international networking and education platform aiming to facilitate the development of new immunotherapies against cancer for the benefit of patients. CIMT was founded in 2002, and has its home office in Mainz, Germany. The association hosts the largest European expert meetings on cancer immunotherapy, publishes therapeutic guidelines and has established two topic-specific working groups: the CIMT Regulatory Research Party, focusing on the regulatory aspects of drug development, which is pioneering the regulatory framework of actively personalized vaccines for single patient use only; and the CIMT Immunoguiding Program (CIP), which focuses on the quality control and harmonization of immunomonitoring assays. To reach its goals, CIMT closely cooperates with various international partners. Visit www.cimt.eu for more information.