



Siemens and BioNTech cooperate on production of personalized cancer vaccines

- **Strategic collaboration for the GMP production of personalized medicine**
- **Development and construction of an automated and paperless manufacturing site**
- **Integration of all necessary process and production steps for manufacturing Individualized Vaccines against Cancer (IVAC®)**

Mainz, Germany, 25 June 2015: Siemens and BioNTech AG, a fully integrated biotechnology company developing truly personalized cancer immunotherapies, have entered into a strategic collaboration. BioNTech AG's subsidiaries, BioNTech RNA Pharmaceuticals GmbH and EUFETS GmbH, will work together with Siemens on the construction of a fully automated and digitalized production site to provide capacity for BioNTech's truly personalized cancer vaccines to serve worldwide markets. The cooperation will enable BioNTech to establish and integrate all necessary process and production steps for manufacturing its IVAC® individualized vaccines at a larger scale.

This strategic collaboration brings together each partner's specific competences in order to optimize automation and digitalization technology for a paperless, commercial-scale GMP (Good Manufacturing Practice) manufacturing of truly personalized medicines.

Ugur Sahin, CEO of BioNTech, said: "We are pleased to partner with Siemens on automating a specialized, proprietary manufacturing process for truly personalized medicine. Siemens' world-class expertise in engineering and optimizing automatic manufacturing processes will be of great value in making personalized cancer treatment for patients available to all."

Eckard Eberle, CEO of the Siemens Business Unit Process Automation, added: "The development and manufacturing of personalized medicine is connected with massive amounts of data. Solutions such as our manufacturing operations management (MOM) software are able to handle the complexity of this innovative new process technology. Together with BioNTech's competence in individualized medicine, we will pave the way for a digital plant with an efficient and completely paperless production."

The IVAC® MUTANOME Immunotherapy approach is based on targeting the unique mutation signature of an individual patient's tumor. It is engineered on demand and administered as an individual treatment. IVAC® MUTANOME is currently in a Phase I/IIa clinical trial for the treatment of malignant melanoma.

Siemens offers a paperless manufacturing solution for enhancing both efficiency and product quality, while at the same time bringing down costs. Fully integrated communication is established between the automation level and manufacturing IT. As a central access point for all process and quality relevant data, the solution links advanced scheduling with the manufacturing execution and the laboratory management



system. This enables complete electronic recording and documentation of quality-related production data, while eliminating time-consuming manual procedures and paper-based batch reports. Paperless manufacturing thus accelerates the design, execution, review and release of pharmaceutical production processes and electronic batch records (EBRs).

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Notes to editors

About BioNTech AG

BioNTech AG is an immunotherapy leader with bench-to-market capabilities, developing truly personalized, well-tolerated & potent treatments for cancer and other diseases. Established by clinicians and scientists, the Group is pioneering disruptive technologies ranging from individualized mRNA based medicines through innovative Chimeric Antigen Receptors /T-cell Receptor-based products and novel antibody checkpoint immunomodulators. BioNTech's clinical programs are supported by an in-house molecular diagnostics unit whose products include MammaTyper[®], a molecular in-vitro diagnostic kit marketed under CE and IVD marking in Europe and certain other countries. Founded in 2008, BioNTech is privately held, with Strüngmann Family Office as a majority shareholder. Information about BioNTech is available at www.biontech.de.

About BioNTech RNA Pharmaceuticals GmbH

BioNTech RNA Pharmaceuticals GmbH is a fully-owned subsidiary company within the BioNTech AG Group. The company is a technology leader in the rapidly growing field of synthetic messenger RNA (mRNA) therapeutics. Its system is based on the precise delivery of potent, long-lived synthetic mRNA into target cells. Following delivery of the mRNA, patients' cells produce the mRNA-encoded protein, which is the pharmacologically active product. BioNTech is currently performing clinical trials to develop the concept of tailored multivalent Mutanome Vaccines.

About EUFETS GmbH

Founded in 1997, EUFETS GmbH specializes in services for innovative therapeutic approaches. In 2009, EUFETS became a 100% subsidiary of BioNTech AG, endowing BioNTech with synergistic platforms and complementary expertise for development, testing and manufacturing services. Based on extensive



expertise in molecular biology, virology and cell biology as well as an understanding of the regulatory prerequisites, the major goal of EUFETS is the support of clients developing innovative gene and cell therapies through development, testing and manufacturing services.

About IVAC[®] MUTANOME

Every cancer has an exclusive mutation signature resulting in a specific tumor antigen expression pattern, which makes every tumor absolutely unique. These tumor characteristics are used to generate treatments optimally attacking each tumor. The Individualized Cancer-immunotherapy (IVAC[®]) platform uses tumor-specific information and tailors each patient's personalized RNA-based immunotherapy to activate the immune system of each patient to recognize, target, strike and combat his or her individual cancer. The concept allows for the design, manufacturing and distribution of the custom-made IVAC[®] vaccines for each individual patient. BioNTech was first in bringing this truly personalized therapy into clinical trial phase.

About Siemens AG

Siemens AG (Berlin and Munich) is a global technology powerhouse that has stood for engineering excellence, innovation, quality, reliability and internationality for more than 165 years. The company is active in more than 200 countries, focusing on the areas of electrification, automation and digitalization. One of the world's largest producers of energy-efficient, resource-saving technologies, Siemens is No. 1 in offshore wind turbine construction, a leading supplier of combined cycle turbines for power generation, a major provider of power transmission solutions and a pioneer in infrastructure solutions as well as automation, drive and software solutions for industry. The company is also a leading provider of medical imaging equipment – such as computed tomography and magnetic resonance imaging systems – and a leader in laboratory diagnostics as well as clinical IT. In fiscal 2014, which ended on September 30, 2014, Siemens generated revenue from continuing operations of €71.9 billion and net income of €5.5 billion. At the end of September 2014, the company had around 343,000 employees worldwide on a continuing basis. Further information is available on the Internet at www.siemens.com