Press Release September 21, 2016



## BioNTech to enter into worldwide strategic collaboration with Genentech to develop individualized mRNA cancer therapies

Collaboration will draw upon Genentech's leading position in cancer immunotherapy and BioNTech's premier clinical mRNA vaccine platform

**Mainz, Germany, September 21, 2016** - BioNTech AG, a fully integrated private biotechnology company developing personalized cancer immunotherapies, today announced that it will enter into a worldwide strategic collaboration with Genentech, a member of the Roche Group, to develop, manufacture and commercialize novel messenger RNA (mRNA)-based, individualized cancer vaccines. The collaboration will combine Genentech's leading cancer immunotherapy portfolio and research program with BioNTech's proprietary mRNA cancer vaccine technology platform, and personalized medicine expertise. Together, the two companies will develop individually tailored cancer immunotherapies against a broad range of cancers to potentially provide a new treatment paradigm for cancer patients.

The collaboration will focus on the development of mRNA cancer vaccines targeting neoantigens, based upon BioNTech's Individualized Vaccines Against Cancer (IVAC®) MUTANOME clinical platform for the potential treatment of multiple cancers. A patient's cancer genome can be rapidly sequenced with next generation technology to define a spectrum of unique mutations known as "neoantigens" or "neoepitopes" present in a particular patient's tumor (the "mutanome"). An mRNA vaccine encoding selected neoepitopes can be manufactured for each individual tumor's mutanome signature, which may trigger an immune response highly specific to the tumor resulting in precisely targeted cancer cell death.

Initial clinical development will focus on combination studies using IVAC<sup>®</sup> MUTANOME in a variety of cancer types.

Under the terms of the agreement Genentech will pay BioNTech \$310 million in upfront and near-term milestone payments. The two companies will equally share all development costs and any potential profits for certain programs under the agreement. BioNTech has the right to co-promote certain products that arise from the agreement in the United States and certain countries, including Germany and other major European markets. Under certain circumstances, BioNTech may have sole commercialization rights for other products that Genentech elects not to commercialize. BioNTech will manufacture mRNA cancer vaccines for clinical studies. Genentech will manufacture ommercial product as part of the global supply network.

**Professor Dr. Ugur Sahin, CEO of BioNTech AG** commented: "We are delighted to collaborate with a leading cancer immunotherapy company such as Genentech. Supported by its extensive tumor immunology understanding, BioNTech has been building clinical experience with its proprietary mRNA vaccines in a number of cancer types over several years. Combining BioNTech's broad proprietary capabilities in the design, formulation, manufacturing and clinical testing of individualized neoantigenbased mRNA vaccines with Genentech's eminent cancer immunotherapy, diagnostic, manufacturing and commercial expertise, will allow us, on a global scale, to drive forward the development of individualized vaccines to the market to treat a broad range of cancers."

**Sean Marett, COO of BioNTech** added: "This alliance underpins BioNTech's strategy of collaborating with companies that are committed to developing truly disruptive immunotherapies and its long term ambitions of bringing its own products to market."

"Unlike any medicine we have ever developed, virtually all cancer patients may potentially benefit from a custom built cancer vaccine," said **James Sabry, M.D., Ph.D., Senior Vice President and Global Head of Genentech Partnering**. "By collaborating with BioNTech on this cutting edge approach, we hope to truly advance cancer treatments by using a common molecular backbone – mRNA – that is uniquely tailored to an individual patient."

BioNTech will continue to develop its non-neoepitope mRNA cancer vaccines outside of the collaboration.

The completion of the agreement is subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, and is expected to occur in the fourth quarter of 2016.

## For more information, please contact:

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## About BioNTech AG

BioNTech AG is an immunotherapy leader with bench-to-market capabilities, developing truly personalized, well-tolerated and 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 and shareholders include the MIG Fonds, Salvia, and the Strüngmann Family Office, with the Strüngmann Family Office as the majority shareholder.

Information about BioNTech is available at <u>www.biontech.de</u>.