BioNTech and Shuwen announce partnership to commercialize MammaTyper® in China

- Strategic partnership to commercialize BioNTech’s mRNA-based molecular breast cancer stratification test MammaTyper® in China
- Shuwen to undertake clinical study for Chinese regulatory approval and become exclusive distributor in China
- Partners combine their expertise in in-vitro diagnostics and clinical testing services to allow precise characterization of breast cancer tumor types


Under the terms of the agreement, Shuwen will undertake clinical studies for regulatory approval of MammaTyper® in China, and will become the exclusive distributor in China.

BioNTech’s CE-IVD marked MammaTyper® test is a molecular diagnostic test for stratification of breast cancer by molecular subtyping of routine tumor tissue samples. Based upon precise measurements of gene expression by RNA analysis, MammaTyper® has the potential to significantly improve the standard of diagnosis and ultimately treatment of breast cancer patients.

Correct identification of the molecular subtype of breast cancer is a prerequisite for optimal treatment of patients. With over 200,000 newly detected breast cancer cases every year in China, making MammaTyper® available in China will offer an essential diagnostic tool for the personalized treatment of breast cancer in China.

Dr. Sierk Poetting, CFO of BioNTech AG and Managing Director of BioNTech Diagnostics commented: “We are very pleased to partner with Shuwen Biotech. BioNTech is committed to making truly personalized medicine broadly available in oncology and this partnership offers a unique opportunity to access the Chinese market through Shuwen, a highly innovative and rapidly growing company, allowing MammaTyper® to be used in one of the largest populations in the world. This is a strategic long term cooperation to establish and strengthen our position in the Chinese oncology diagnostics market and will pave the way for launching our own personalized immunotherapies for the treatment of cancer in China.”

Jay Z. Zhang, Chairman and Chief Executive Officer of Shuwen Biotech Co. Ltd, added: “Through in-licensing and international collaborations, Shuwen aims to benefit the Chinese people with a full menu of the most innovative diagnostic tests for disease prevention, diagnosis and treatment. We are on track to deliver on this strategy. The partnership with BioNTech provides an exceptional opportunity for Shuwen Biotech to expand its portfolio in cancer testing.”

The application of MammaTyper® in China as well as globally has the potential to significantly improve the standard treatment of breast cancer patients. Importantly, the test has wide applicability and all breast cancer patients may benefit from molecular cancer subtyping using MammaTyper®. The molecular diagnostics test is highly reproducible and accurate, and overcomes the problem of subjective interpretation that occurs with current testing methods. MammaTyper® is accompanied by RNXtract®, a CE/IVD marked sample preparation kit from FFPE tissue samples.
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 www.biontech.de.

About BioNTech Diagnostics GmbH

BioNTech Diagnostics is a fully-owned subsidiary company within the BioNTech AG Group. The ISO 9001/13485 certified company has extensive product and service offerings ranging from biomarker discovery and validation through molecular screening assays, patient stratification and companion diagnostics to clinical monitoring, all to international regulatory standards. Early detection of diseases that have a high mortality rate and the appropriate selection of therapies are crucial for a successful treatment of patients. BioNTech Diagnostics’ mission is to provide new and innovative diagnostic tests to extend lives of patients, improve their quality of life and support the use of appropriate therapy for each individual patient.

About Shuwen Biotech Co. Ltd.

Based in China and led by U.S. diagnostic industry veterans, Shuwen Biotech is engaged in licensing, developing, marketing and distributing innovative products and services for disease diagnosis and personalized medicine. The company strives to provide China’s doctors and their patients with a comprehensive menu of the most innovative diagnostic products and services for improved disease prediction, screening, diagnosis, prognosis and treatment. Shuwen offers, in China, molecular diagnostic kits and LDT services for personalized medicine in cancer and other diseases. More information about Shuwen Biotech Co. Ltd. can be found at www.shuwenbiotech.com.