Molecular breast cancer subtyping: study confirms advantages of the *in vitro* diagnostic test kit MammaTyper® over immunohistochemistry (IHC)

**Mainz, Germany, June 16, 2016:** BioNTech Diagnostics GmbH, a subsidiary of BioNTech AG, announces the publication of new study data that prove the significant advantages of the *in vitro* diagnostic test kit MammaTyper® (CE / IVD marked) over the currently established methods of detection used in breast cancer subtyping [1]. In the prospective-retrospective study, MammaTyper® achieved ground-breaking results with precise quantitative detection of the biomarkers ERBB2 (HER2), ESR1 (ER), PGR (PR) and MKI67 (proliferation marker Ki-67). It must be emphasized particularly that MammaTyper® was superior to immunohistochemistry with regard to the prognosis when measuring MKI67 (Ki-67). Thus the study shows that MammaTyper® ensures patient stratification as recommended by the St Gallen criteria, including reliable measurement of proliferation by MKI67. “The positive study data for MammaTyper® underline our commitment to making personalized medicine broadly available for treating cancer”, added Dr Sierk Poetting, Managing Director at BioNTech Diagnostics.

Over the past few years, the IHC method has been discussed time and again by expert groups with regard to its reproducibility, objectivity and comparability. Differences do arise, particularly when measuring the proliferation marker Ki-67 which is used, for example, to differentiate between luminal A and luminal B tumours, among other things [2-5].

Previous studies have already shown that molecular detection of mRNA expression of the markers by RT-qPCR (reverse transcription quantitative real time polymerase chain reaction), on which the in vitro diagnostic test kit MammaTyper® is also based, have significant advantages over IHC [6-8].

The recently published prospective-retrospective randomized MammaTyper® clinical study [1] enrolled a total of 769 patients from the FinHer study [9]. It was the first to compare quantitative measurements of tumour ESR1-, PGR-, ERBB2- and MKI67-mRNA using MammaTyper® with the results of ER-, PR-, and Ki-67 protein expression by IHC or of HER2 by chromogenic *in situ* hybridization (CISH). The results were correlated with disease-free survival and the overall survival period. The data show that quantitative measurement of ESR1- and PGR- and ERBB2-mRNA by MammaTyper® correlates with the results from IHC and *in situ* hybridization in pathology laboratories [ER/ESR1: 92 %, p < 0.0001; PR/PGR: 83 %, p < 0.0001 and HER2/ERBB2: 92 %, p < 0.0001, OPA].

Measurements of MKI67 mRNA expression with MammaTyper® showed that patients who express a low level of MKI67 have a significantly better prognosis with regard to disease-free survival and overall survival than patients with a high MKI67 expression. In contrast, measurement of Ki-67 protein expression by IHC showed no significant difference between these two groups for the prognosis of the two parameters.
The study also showed that the patients identified as luminal B by MammaTyper® who were treated with docetaxel FEC had a more favourable prognosis for disease-free survival and overall survival than those who were treated with vinorelbine FEC. The IHC results were not able to show this relation between subtype and response to the medication. This means that, compared to IHC, breast cancer subtyping by MammaTyper® opens up new opportunities of providing predictive information about the benefits of adjuvant taxane treatment.

In summary, the study clearly shows that, in comparison to established methods, MammaTyper® allows a precise biomarker measurement method that can be standardized and, due to the reliable detection of Ki-67, provides better indications of the need for and benefits of chemotherapy.

*OPA: Overall percent agreement

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Notes to editors

About MammaTyper®

MammaTyper® is a molecular in vitro diagnostic test for quantitative detection of the mRNA expression status of the genes ERBB2 (HER2), ESR1 (ER), PGR (PR) and of MKI67 (proliferation marker Ki-67) in the tumour tissue of female patients with newly diagnosed invasive breast cancer. The test has been validated for total RNA extracted from tissue specimens or biopsies.

MammaTyper® is used for molecular subtyping of breast cancer tissue according to the St. Gallen classification (2013) in luminal A-like, luminal B-like (HER2 negative), luminal B-like (HER2 positive), HER2 positive (non-luminal) and triple negative (ductal) tumours, and offers the possibility of significantly improving the diagnosis and, ultimately, the treatment of female patients with breast cancer. MammaTyper® is intended for use by a doctor together with further clinical pathological factors. The test is very simple, and can be carried out in any pathology laboratory. The test can be used on all female patients with newly diagnosed invasive breast cancer and provides the results on the same day. With MammaTyper®, BioNTech underlines its commitment to making personalized medicine generally available in the field of cancer treatment. Information about MammaTyper® is available at www.mammatyper.com.
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, with Strüngmann Family Office as a majority shareholder, having closed the largest initial financing in the European biopharma sector’s history. 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.

References


9 FinHer-Studie, identifier ISRCTN76560285)