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Company Announcement

MPI publishes data showing that MPI's product Drug Response Predictor may help to identify patients with tumors more likely to respond to fulvestrant

- **MPI again successful with its broadly applicable Drug Response Predictor (DRP) for cancer drugs**
- **MPI's DRP can generate clinically relevant gene signatures and can be a strong drug development tool**

Hoersholm; 5 February 2014 - Medical Prognosis Institute A/S (MPI) publishes data in PLOS ONE showing that a tumor-derived mRNA signature produced by MPI's product Drug Response Predictor (DRP) may help to identify tumors that are more likely to respond to fulvestrant. PLOS ONE is an international, peer-reviewed, open-access, online publication in which the results appear under the title "Development and validation of a gene expression score that predicts response to fulvestrant in breast cancer patients."

Summary
Not all cancer patients benefit from cancer drugs. The PLOS ONE publication shows that it is possible to utilize the MPI DRP tool to generate a signature that may help identify breast cancer patients that may benefit from pre-surgical treatment with the endocrine agent fulvestrant. The prediction method is based on observations of differences in gene expression between cancer cell lines that are sensitive and those that are resistant to fulvestrant. The differential gene expression signature from cell lines was then applied to tumor tissue from a small cohort of breast cancer patients who participated in a clinical trial that involved neoadjuvant treatment of the patients with fulvestrant. Additional retrospective testing of this gene signature in a larger cohort of patients with early stage breast cancer will be required to gain a greater understanding of the predictive power if the signature in identifying patients with tumors more likely to respond to fulvestrant. The goal is to develop the gene signature into a diagnostic that may aid in the identification of patients more likely to benefit from treatment with fulvestrant.
For full article please view: http://dx.plos.org/10.1371/journal.pone.0087415

"*The initial data published in PLOS ONE with fulvestrant provides some evidence that MPI's DRP can be utilized as a strong drug development tool to generate signatures that can help predict response*," said CEO Peter Buhl Jensen. "*The DRP is a fixed system that can be applied in the process of identifying relevant clinical indications and identify those patients who are most likely to benefit from the drug. The MPI DRP can be applied for a huge number of the many cancer drugs and cancer indications where no biomarkers are available. It can be supplemented and add clinical relevant information for the doctors when deciding the best treatment for the patient.*" Buhl Jensen further added.

About the clinical study with fulvestrant

NEWEST (Neoadjuvant Endocrine Therapy for Women with Estrogen-Sensitive Tumors; 9238IL/0065) was a randomized, open-label, multicenter, Phase II study involving postmenopausal women with newly diagnosed, ER positive, locally advanced breast cancer who had received no prior breast cancer treatment (NCT0093002). Eligible patients were randomized 1:1 to receive either fulvestrant 500 mg or 250 mg for 16 weeks preceding surgery. The endpoint was response as per RECIST criteria. 42 patient samples were available and qualified for the prediction analysis.

About DRP

MPI's lead product DRP (Drug Response Predictor) is a tool to develop tumor-derived gene signatures that may predict which cancer patients are high likely responders to a given anticancer product. The DRP has been tested in 24 trials where 20 trials were positive. The DRP has also been externally validated and published in collaboration with leading statisticians at the MD Anderson Cancer Center.

The DRP method can also be used to design the Clinical Development Plan i.e. to select which indications are relevant for a given anticancer drug. Further to and in addition to this, individual patient's gene patterns can be analyzed as part of a screening procedure for a clinical trial to ensure inclusion of patients who have a high likelihood of response to the drug. The DRP method can be used in all cancer types and has been patented for more than 60 anticancer drugs in the US in 2013.

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About MPI
MPI is an IT– Medico company with a proprietary method to predict patients sensitivity towards a given anticancer drug by its Drug Response Prediction a gene-tests on tumours. MPI's customers are Pharma and biotech engaged in developing anticancer drugs. MPI's technology has derived from data from more than 3.000 patient's tumours and are validated in 24 clinical studies. The test is broadly applicable in all cancer types and for almost all anticancer therapies. The test is believed to be of high value especially for the very large group of cancer patients for whom there are no other bio-markers available.