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Company Announcement – No. 98

Successful US patent strategy – Oncology Ventures Irofulven Claims Accepted

Hoersholm; May 29th, 2017 - Medical Prognosis Institute (MPI:ST) today announced that Oncology Venture a spinout from MPI using MPI's DRP technology for drug development was informed by the US Patent Office that it will allow the claims in a patent application for a response predictor (DRP™) for Oncology Ventures anticancer drug Irofulven. A patent will be issued by the US Patent Office in the near future.
The Orange Book allows listing of biomarker patents that are required for the screening of patients for treatment with a specific drug. After that, a generic drug cannot be filed to replace Irofulven for as long as the biomarker patent is valid.

"The granting of the patent on Irofulven in combination with its DRP is supporting MPI's patent strategy as Irofulven is now protected by for 20 years by the listing in the FDA Orange Book," ***Peter Buhl Jensen, M.D., CEO of MPI commented.***

Oncology Venture is developing the phase 2 drug candidate Irofulven, together with a companion diagnostic technology (Irofulven DRP™) to identify patients highly likely to respond to Irofulven therapy. The Irofulven DRP™ companion diagnostic is derived from the Drug Response Predictor (DRP™) Platform of Medical Prognosis Institute (MPI) and out-licensed to OV. Previous substantial clinical investigations in 38 clinical trials (19 published) of Irofulven by US biotech company MGI Pharma and pharmaceutical company Eisai led to objective responses in subsets of patients, including for a range of hard to treat cancers; such as prostate, ovarian, liver and pancreatic cancer. Utilizing the DRP Platform, genetic signatures have been identified associated with response to Irofulven.

About The Orange Book
The Orange Book identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act. The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons. Inclusion of products on the List is independent of any current regulatory action through administrative or judicial means against a drug product.
The Orange Book lists patents that are purported to protect each drug. Patent listings and use codes are provided by the drug application owner, and the FDA is obliged to list them. In order for a generic drug manufacturer to win approval of a drug under the Hatch-Waxman Act, the generic manufacturer must certify that they will not launch their generic until after the expiration of the Orange Book-listed patent, or that the patent is invalid, unenforceable, or that the generic product will not infringe the listed patent.

About Irofulven
Irofulven (6-hydroxymethylacylfulvene) is a semi-synthetic derivative of illudin S, a natural toxin isolated from the Jack O'lantern mushroom (Omphalotus illudens). A pro-drug, Irofulven requires catalysis by prostaglandin reductase 1 to become active.
Created at the University of California, San Diego (UCSD), Irofulven was exclusively licensed to US biotech company MGI Pharma, which was acquired by Eisai in 2007. After being returned to UCSD in 2009, Lantern Pharma licensed Irofulven in 2015, and subsequently sub-licensed Irofulven to Oncology Venture.
Irofulven is more active in vitro against tumour cells of epithelial origin and is more resistant than other alkylating agents to deactivation by p53 loss and MDR1. Irofulven exhibits impressive anti-cancer results in xenograft models in vivo, shows synergy with topoisomerase I inhibitors, and has demonstrated activity against cell lines that are resistant to other therapies. Irofulven has significant scope for combination with other therapies, including standard chemotherapeutic regimes.

About MPI's multiple biomarker called Drug Response Predictor - DRP™
MPI's DRP™ is a tool for developing tumor-derived genetic signatures to predict which cancer patients are high likely to respond to a given anti-cancer product. The DRP™ has been tested in 37 trials, where 29 trials showed that drug-specific DRP™ Biomarkers could predict which patients responded well to the treatment. The DRP™ platform has amongst others been externally validated and published in collaboration with leading

statisticians at the MD Anderson Cancer Center. The DRP™ method can be used to design the Clinical Development Plan, i.e. to select which indications are relevant for a given anti-cancer drug. In addition to this, the individual genetic patterns of patients can be analyzed as part of a screening procedure for a clinical trial to ensure inclusion of patients with a high likelihood of response to the drug. DRP™ builds on comparison between sensitive and resistant human cancer cell lines, including genomic information from cell lines combined with clinical tumor biology and clinical correlates in a systems biology network. The DRP™ is a Big Data tool based on messenger RNA.
The DRP™ platform can be used in all cancer types, and has been patented for more than 70 anti-cancer drugs in the US.

About MPI

Medical Prognosis Institute a publicly traded international company specialized in improving cancer patients lives by developing Personalized Medicine using its unique DRP™ technology. MPI's exceptional opportunity to personalize cancer treatment - begins with Breast Cancer moving on to Multiple Myeloma and Prostate Cancer as the first steps. MPI's DRP™ tool has shown its ability to separate patients who benefit and who do not benefit from a specific cancer treatment. This has been shown in as many as 29 out of 37 trials, and covers more than 80 anti-cancer treatments in a wide range of cancer indications. MPI has built a significant large database with over 1,000 screened breast cancer patients and is building up a database in Multiple Myeloma to be followed by Prostate cancer in collaboration with oncologists and hematologists throughout Denmark.

* *Adjuvant systemic therapy in early breast cancer: impact of guideline changes and clinicopathological factors associated with nonadherence at a nation-wide level*. A. M. F. Verschoor et al. Published online: 12 August 2016 Springer Science+Business Media New York 2016

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