

June 3, 2008

**Preliminary Data from Ongoing Phase 1 Trial of  
Investigational Fully Human Anti-PD-1 Antibody “ONO-4538/MDX-1106”  
Presented at American Society of Clinical Oncology**

Medarex, Inc. (Head Office: New Jersey, US, President & CEO: Howard Pien) announced preliminary data from an ongoing Phase 1 study of “ONO-4538/MDX-1106”, a fully human anti-PD-1 antibody for the treatment of cancer at the 44<sup>th</sup> annual meeting of the American Society of Clinical Oncology (ASCO) being held in Chicago on May 31, 2008 (US time). These data were presented by Julie Brahmer, M.D., an investigator and Assistant Professor of Oncology from the Sidney Kimmel Cancer Comprehensive Center at Johns Hopkins University.

“ONO-4538/MDX-1106” was developed under the May 2005 collaborative research agreement between Ono Pharmaceutical Co., Ltd. (Head office: Osaka, President: Toshiharu Korekane) and Medarex, and is currently being evaluated in Phase 1 clinical studies for cancer and hepatitis C conducted by Medarex in the US.

Ono plans to start a Phase 1 clinical study for cancer in this autumn in Japan.

This is the summary of the press release issued by Medarex for the preliminary clinical data.

- Interim results from this single-dose Phase 1 were reported for patients enrolled with recurrent or treatment-refractory solid tumors, including non-small cell lung cancer, renal, colon, melanoma, and hormone-refractory prostate cancer. The first 36 of the 39 enrolled subjects had been followed long enough for initial efficacy assessments.
- The Phase 1 single-dose study is being conducted to evaluate the efficacy, safety, tolerability and pharmacokinetics of ONO-4538/MDX-1106. Patients received single-dose treatment of ONO-4538/MDX-1106 (0.3, 1, 3 or 10 mg/kg), starting from the lowest dose, and those 11 patients who tolerated treatment and were stable or not progressing rapidly were allowed re-treatment with multiple doses.
- Preliminary evidence of anti-tumor activity was observed. One patient with colorectal carcinoma has experienced a confirmed partial response (>30% decrease in the sum of the tumors' longest diameters) that remains durable for more than 6 months. In addition, tumor regressions (<30% decrease of the sum of the tumors' longest diameters) were also observed in four additional patients, including two patients with melanoma, one patient with non-small cell lung cancer, and one with renal cell carcinoma.
- We planned to assess the dose-limiting toxicities at 4 weeks following single-dose therapy and all doses were well-tolerated with no observed severe immune-related adverse events or dose-limiting toxicities within the first 4 weeks. Two patients with histories of arthritis developed low grade arthritic symptoms that responded to oral corticosteroid treatment.

Of the 11 patients that were eligible for re-treatment, one patient developed colitis nine months after starting therapy, and 3 weeks after his fifth dose of 1 mg/kg but it is improving with treatment after discontinuation of ONO-4538/MDX-1106 dosing.

“We are pleased with the safety profile and preliminary evidence of tumor shrinkage from this first human clinical trial of ONO-4538/MDX-1106,” said Geoffrey M. Nichol, MBChB, Senior Vice President of Product Development at Medarex. “We look forward to the further development of this novel immunotherapy, and plans are underway to initiate a Phase 2 trial of MDX-1106 in cancer this year.”

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**About ONO-4538/MDX-1106**

MDX-1106/ONO-4538 is a novel fully human antibody designed to target and inhibit the function of PD-1 (programmed cell death 1), a receptor expressed on the surface of activated lymphocytes (T-cells) that is involved in the system of negative regulation for the suppression of activated lymphocytes. A number of studies have reported that tumor cells, HCV and HIV use this system to evade immune responses. Blockade of PD-1, a receptor involved in the negative regulatory signal, is expected to recognize tumor cells and viral pathogens as foreign, and promote the host immune response to eliminate them. Preclinical studies suggest that blockade of the PD-1 signaling pathway by ONO-4538/MDX-1106, a fully human anti-PD-1 antibody, activates T-cell responses and promotes an immune response to fight tumors and infectious diseases.

**About Medarex**

Medarex is a biopharmaceutical company focused on the discovery, development and potential commercialization of fully human antibody-based therapeutics to treat life-threatening and debilitating diseases, including cancer, inflammation, autoimmune disorders and infectious diseases. Medarex applies its UltiMab<sup>®</sup> technology and product development and clinical manufacturing experience to generate, support and potentially commercialize a broad range of fully human antibody product candidates for itself and its partners. More than 40 of these therapeutic product candidates derived from Medarex technology are in human clinical testing or have had INDs submitted for such trials, with seven of the most advanced product candidates currently in Phase 3 clinical trials or the subject of regulatory applications for marketing authorization. Medarex is committed to building value by developing a diverse pipeline of antibody products to address the world's unmet healthcare needs. For more information about Medarex, visit its Web site at [www.medarex.com](http://www.medarex.com).

<p>This is a translated brief summary of the press release issued by Medarex on June 2, 2008 (US time), and the contents and interpretation of the original Medarex English version will take precedence over this version.</p>
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For more information on this press release  
Ono Pharmaceutical Co., LTD  
Public Relations  
TEL : 06-6263-5670