June 2, 2009

Data from ongoing Phase 1 expansion cohort and Multi-Dose Phase 1b Trials of Investigational Fully Human Anti-PD-1 Antibody "ONO-4538/MDX-1106" in Cancer Patients at American Society of Clinical Oncology Annual Meeting

Medarex, Inc. (Head Office: New Jersey, US, Chairman & CEO: Howard Pien) announced data from ongoing Phase 1 expansion cohort and multiple dose Phase 1b studies of the investigational drug "ONO-4538/MDX-1106", a fully human anti-PD-1 antibody in cancer patients at the 45th annual meeting of the American Society of Clinical Oncology (ASCO) being held in Orlando, FL on June 1, 2009 (US time).

- These data were presented by Julie Brahmer, M.D., an investigator and Assistant Professor of Oncology from the Sidney Kimmel Comprehensive Cancer 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: Gyo Sagara) and Medarex, and is currently being evaluated in Phase 1 clinical studies for cancer and hepatitis C conducted by Medarex in the US.
Ono is also conducting a Phase 1 clinical study with "ONO-4538/MDX-1106" for cancer in Japan.

This is the summary of the press release issued by Medarex for the clinical data. Results from the Phase 1 expansion cohort and preliminary multi-dose Phase 1b study were reported for patients enrolled with recurrent or treatment-refractory solid tumors, including non-small cell lung cancer (NSCLC), renal, colorectal, melanoma, and prostate cancer.

Single-dose Phase 1 study

- The single-dose Phase 1 study was designed to examine the efficacy, safety, tolerability and pharmacokinetic profile of ONO-4538/MDX-1106. Patients received a single-dose dose of ONO-4538/MDX-1106 (0.3, 1, 3 or 10 mg/kg), starting from the lowest dose. Of 39 patients enrolled to the single-dose Phase 1 study, 12 patients demonstrating tolerability and no marked tumor growth received additional intermittent doses.

- In the single-dose Phase 1 study, one patient with colorectal carcinoma treated with 3 mg/kg ONO-4538/MDX-1106 has maintained a partial response (≥30% decrease in the total of longest diameters of each tumor) for over 20 months, and one patient with renal cell cancer treated with 10 mg/kg ONO-4538/MDX-1106 has maintained a partial response of over 9 months. In addition, tumor regressions (<30% decrease in the total of longest diameters of each tumor) were observed in 3 patients (melanoma: 2, NSCLC: 1).

- The single-dose Phase 1 study was designed to evaluate the dose-limiting toxicities (DLTs) at 4 weeks after administering a single dose of ONO-4538/MDX-1106. ONO-4538/MDX-1106

appeared to be well-tolerated at all doses, and no serious immune-related adverse events or DLTs have been observed within 4 weeks after administrating the initial single dose of ONO-4538/MDX-1106. One patient developed colitis 3 weeks after his fifth dose of 1 mg/kg and was managed medically, but no serious toxicities have been observed in the 6 patients receiving between two and nine doses of 10 mg/kg ONO-4538/MDX-1106.

Multi-dose Phase 1b study

- The multi-dose Phase 1b study is designed to examine the safety and efficacy in patients treated with multiple doses of ONO-4538/MDX-1106 (1, 3 and 10 mg/kg) administered every two weeks. This multi-center, open label study is expected to enroll up to 76 patients in the United States. The efficacy is being evaluated every 8 weeks in this study. Currently, this study is in the early stage of the dose-escalating assessment for the dose limiting toxicity of ONO-4538/MDX-1106.

- In the multi-dose Phase 1b study, one patient with melanoma has demonstrated marked tumor regression of liver and lung lesions after receiving four doses of 1 mg/kg of ONO-4538/MDX-1106. The tumors have continued to shrink after additional four doses. Anti-tumor activity has also been observed with lung lesion regression in a patient with renal cell cancer. One patient with NSCLC has demonstrated regression of a solitary adrenal metastasis after the first 4 doses of 3 mg/kg of ONO-4538/MDX-1106.

“We are encouraged with both the safety profile and the initial anti-tumor activity that included durable responses in several cancer indications for patients treated intermittently with MDX-1106 up to the 10 mg/kg dose. We are also pleased by our ongoing Phase 1b study of repeated doses of the antibody which has also shown early evidence of activity at a repeated dose of 1 or 3 mg/kg,” said Geoffrey M. Nichol, MBChB, Senior Vice President of Product Development at Medarex. “While we are still in early stages of development, it is also exciting that these treatments continue to be generally well tolerated.”

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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). The binding of PD-1 with one of two ligands (PD-L1 or PD-L2) is an important negative regulation pathway that suppresses or inhibits activated lymphocytes. Recent research has noted increased PD-1 expression levels on antigen specific T-cells in both the oncology and chronic infectious disease settings, as well as a strong correlation between increased PD-L1 expression on tumors and a negative survival prognosis in cancer patients. Preclinical studies indicate that antibodies targeting the PD-1 signaling pathway reinvigorate antigen-specific T-cell responses and promote 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® 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. Over forty of these therapeutic product candidates derived from Medarex technology are in human clinical testing or have had INDs submitted for such trials, with the most advanced product candidates currently approved for commercial sale, the subject of regulatory applications for marketing authorization or in Phase 3 clinical trials. 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 website at www.medarex.com.

This is a translated brief summary of the press release issued by Medarex on June 1, 2009 (US time), and the contents and interpretation of the original Medarex English version will take precedence over this version.

For more information on this press release
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