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Public Relations

Ono Pharmaceutical Co., Ltd.

Tel: +81-6-6263-5670

Fax: +81-6-6263-2950

Ono and Medarex Enter Into Collaborative Research Agreement on Antibody Product

Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President: Kimiichiro Matsumoto) announced today that the company signed a collaborative research agreement with Medarex, Inc. (Headquarters: Princeton, New Jersey, the US; President and CEO: Donald L. Drakeman) to research and develop a fully human anti-PD-1 antibody for the potential treatment of cancer. The parties have already started generating fully human anti-PD-1 antibody product candidates under Ono's intellectual property regarding PD-1 and using Medarex's proprietary UltiMAb Human Antibody Development System®, and they expect that clinical studies could begin in 12 to 24 months.

Under this arrangement, Ono and Medarex will jointly work toward potential commercialization of an anti-PD-1 antibody. The two companies plan to share the costs and responsibilities of research and product development up to the completion of a Phase II clinical study. Thereafter, each company will be fully responsible for any continued development and any commercialization in its exclusive territory; Medarex's exclusive territory is North America, and Ono's exclusive territory is all areas outside of North America.

PD-1 is one of the receptors expressed on the surface of activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses (which protect an individual from both harmful pathogens and the individual's own altered cells (tumors)). It is anticipated that the blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells are recognized as foreign and eliminated. The Medarex/Ono antibody has been designed to block this signaling pathway in order to potentially enhance the ability of the patient's immune system to attack the cancer cells.

***Comments from Medarex**

Dr. Donald L. Drakeman, President and CEO of Medarex said: "We are pleased to be able to join with Ono to advance this potentially important new product candidate for the treatment of cancer."

***Comments from Ono**

Dr. Kigen Kondoh, Executive Director of Research Headquarters at Ono said: "We have performed functional research with various genes encoding secreted proteins, which were isolated in the course of exploration of innovative physiologically active substances and discovery targets. PD-1 is one of our gene assets resulting from such exploratory research. We expect to significantly expand the potential development of pharmaceutical products against this novel discovery target through our collaboration with Medarex."