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Chugai Pharmaceutical Co., Ltd.
Dainippon Sumitomo Pharma Co., Ltd.

Joint Development of Therapeutic Cancer Vaccine WT4869

Chugai Pharmaceutical Co., Ltd. (Head Office; Tokyo, Japan; President; Osamu Nagayama: hereinafter called “Chugai”) and Dainippon Sumitomo Pharma Co., Ltd. (Head Office; Osaka, Japan; President; Masayo Tada: hereinafter called “DSP”) announced today that the two companies will jointly conduct a Phase I/II clinical study of WT4869 in Japan, a therapeutic cancer vaccine for the treatment of patients with myelodysplastic syndromes (MDS).

The WT1 protein, a product of the Wilm's tumor gene 1, is known to be highly expressed in leukemia and most solid tumors, as investigated by the group of Dr. Haruo Sugiyama, Professor of Osaka University Graduate School of Medicine. It has been suggested that WT1 functions as a cancer antigen, and peptides derived from the WT1 protein have been tested for potential application in cancer immunotherapy. Based on basic and clinical research results from studies by Prof. Sugiyama and his group, Chugai and DSP have developed a novel peptide WT4869 in their collaborative development program to be applied as a therapeutic cancer vaccine targeting various types of tumors. It is expected that administration of WT4869 will show efficacy in the treatment of leukemia and other types of cancers that express WT1, by inducing WT1-specific cytotoxic T-lymphocytes that have the potential to attack tumor cells.

MDS is a type of hematological cancers and in general refractory to most therapeutic treatments. The disease is attributable to clonal growth of hematopoietic stem cells associated with gene abnormalities, and is clinically characterized by cytopenia and a risk of rapid progression to acute myeloid leukemia during the course of disease. The number of MDS patients in Japan is approximately 7,100 with a prevalence of 2.7 patients per 100,000 persons according to a national survey in 1998, and the number is thought to be on the rise. As there is currently no established standard treatment option other than bone-marrow transplantation, MDS has a high unmet medical need and development of novel treatment options are greatly in demand in Japan.

Chugai and DSP wish to contribute to better treatment of MDS by promoting the development of WT4869 in their joint development program. Both companies anticipate that the range of indications of WT4869 will be expanded to other types of cancer as well.

(Reference)

Peptide cancer vaccine therapy:

Peptide cancer vaccine is a treatment option in which patients' immune cells are potentiated by administration of a tumor antigen peptide (a protein fragment) to combat tumor cells.

Prof. Sugiyama and his colleagues discovered that WT1 is associated with development of various cancers, and they have published their findings from basic research on WT1 peptide vaccination in the *Journal of Immunology* in 2000 (February 15, 2000 issue).