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Press Release,

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Announcement of the initiation of a phase II clinical trial of the cancer peptide vaccine GRN-1201 with the concomitant use of an immune checkpoint antibody against non-small cell lung cancer in the United States

We are pleased to announce the initiation of a phase II clinical trial of the cancer peptide vaccine GRN-1201with the concomitant use of an immune checkpoint antibody against non-small cell lung cancer (NSCLC)[*1] in the United States.

GRN-1201 is a cancer peptide vaccine that consists of peptides derived from 4 cancer antigen proteins and recognizes HLA-A2, which is a common HLA[*2] type in Americans and Europeans. We are conducting phase I clinical trial of GRN-1201 targeted to melanoma in the United States and have obtained safety information to initiate this second study. This time, we newly launch a phase II clinical trial of the concomitant use of GRN-1201 with an immune checkpoint antibody (an anti-PD-1 antibody preparation). The therapeutic effect of immunity is expected to be enhanced further by the concomitant use of a cancer vaccine that activates immune functions and an immune checkpoint antibody that removes the brakes on the immune system. This trial is scheduled to be performed as an open label study with the overall response rate (ORR)[*3] as a primary endpoint from 2017 to 2019.

Lung cancer ranks first among the causes of cancer deaths in the world, claiming the lives of about 160,000 people in the United States[*4] and about 70,000 people in Japan.[*5] Although immune checkpoint antibodies have been approved and have aroused great expectations as a trump card in the treatment for lung cancer, they are ineffective except for patients in whom immunity against cancer has been established, who are estimated to account for 20-30% of all cancer patients. We, therefore, have decided to carry out this trial, aiming to elicit therapeutic effects in more cancer patients by the concomitant use of an immune checkpoint antibody with a cancer vaccine, such as GRN-1201, that helps with the establishment of cancer immunity in the patients.

This matter will have minimum impact on business results for the fiscal year ending in March 2017.

Explanation of terms

*1 Non-small cell lung cancer (NSCLC): Lung cancers are generally divided into two main categories: small cell lung cancer (SCLC) and NSCLC. NSCLC progresses more slowly than SCLC, and tends to have a lack of response to chemotherapy or radiotherapy. In Japan, ≥80% of lung cancers are NSCLC. NSCLC is classified into more specific subtypes, including adenocarcinoma, squamous cell carcinoma, and large cell carcinoma.

*2 Human leukocyte antigen (HLA): It is a protein that is expressed on the surface of nearly all cells of the body and plays an important role in the immune system. It is also called major histocompatibility complex. HLA is a self/non-self identification marker that distinguishes the self from non-self (others) and has various types to distinguish a great diversity of "others" from the self. Peptides bind to specific types of HLA.

*3 Overall response rate (ORR): The percentage of the patients who have shown a decrease in size or disappearance of cancer after the administration of a particular treatment.

*4 Estimate for 2017. Cited from the website of the American Cancer Society (http://www.cancer.org/cancer/lungcancer-non-smallcell/detailedguide/non-small-cell-lung-cancer-key-statistics).

*5 2014. Cited from the Cancer Registry/Statistics of the National Cancer Center Japan, Cancer Information Service

About GreenPeptide Co., Ltd.

GreenPeptide is a drug discovery venture company responsible for the development of innovative "cancer immunotherapy" as the 4th cancer treatment following surgery, radiotherapy, and chemotherapy. Clinical trials on cancer peptide vaccines are being conducted in Japan and the United States, and we recently started the development of new T-cell therapy involving the iPS regeneration of antigen-specific T cells. We have also announced the development of new drugs using neoantigens, which is a highly novel approach in the world.