Press Release

November 4, 2015

GreenPeptide Receives Clearance from FDA to Proceed with Phase 1 Clinical Trial for Its Therapeutic Cancer Vaccine GRN-1201

GreenPeptide Co., Ltd. (TSE Mothers Code: 4594), a clinical-stage biopharmaceutical company focused on development of novel cancer immunotherapies, today announced that its Investigational New Drug (IND) application for a Phase 1 clinical study with a therapeutic cancer vaccine GRN-1201 has been cleared by the United States Food and Drug Administration (FDA). GRN-1201 will be tested in patient with melanoma.

The GRN-1201 cancer vaccine is a combination of four HLA-A*02 restricted peptides derived from four separate tumor associated antigens presented in cancer cells and required by cancer cells to grow and survive.

Assuming future out-license to multi-national pharmaceutical companies, the Phase 1 study will be conducted as GRN-1201 monotherapy in patients with malignant melanoma as an initial indication, followed by clinical trials in combination with other cancer immunotherapies, especially with immune checkpoint inhibitors, and for additional indications in the future.

Food and Drug Administration (FDA): The FDA is an agency within the U.S. Department of Health and Human Services. FDA is responsible for protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices. FDA is also responsible for regulatory approval of drugs to be sold in the U.S. market, and regulates its development process and approvals.

Investigation New Drug (IND) filing: The IND is the means through which the sponsor technically obtains the exemption from the FDA to run clinical studies in the U.S.A. IND is a document package in which information on safety and quality data of candidate drug is provided, and it explains why the drug may be efficacious and safe to be tested in human. After submission of an IND, the FDA carries out an examination in order to ensure the safety and human rights of study participants, and FDA is required to complete this process within 30 days.

Human Leukocyte Antigen (HLA): HLA is a protein that plays important roles in immune function, and is expressed on the surfaces of most cells in the human body. It is also termed the “major histocompatibility complex”.
HLA is a self/other recognition marker, enabling one’s own body to be distinguished from other entities, and, as there is very great variety in the “other”, it occurs in extremely diverse forms enabling them all to be distinguished from the “self”. Peptides bind with specific forms of HLA, and do not bind with form that do not match.

Malignant melanoma: Malignant melanoma is a potentially serious type of skin cancer. The 5-year survival rate is 16.1% particularly for advanced malignant melanoma that has spread to other parts of the body (SEER 2004-2010 and SEER Summary Stage 2000). In 2014, it's estimated 76,100 new cases diagnosed of and 9,710 deaths from melanoma in the U.S. Remarkable progress has been achieved in cancer immunotherapy for melanoma after the approval of immune checkpoint inhibitor antibody ipilimumab in 2011, followed by those of pembrolizmab and nivolumab in 2014.

Type of Cancer	New Cases 2014, US	Deaths 2014, US
1. Prostate Cancer	233,000	29,480
2. Breast Cancer (for Woman)	232,670	40,000
3. Lung/bronchial Cancer	224,210	159,260
4. Colorectal Cancer	136,830	50,310
5. Melanoma Skin Cancer	76,100	9,710
6. Bladder Cancer	74,690	15,580
7. Non-hodgkin Lymphoma	70,800	18,990
8. Cancers in the pelvis (the liver, the kidney)	63,920	13,860
9. Thyroid Cancer	62,980	1,890
10. Cervical Cancer	52,630	8,590

Source: National Cancer Institute 2014

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