Clinical Results for Dendritic Cell Vaccine Vaccell® Announced in Cancer Science
~Evaluation of the feasibility and immune response of Vaccell® pulsed with WTI peptides for treating advanced pancreatic cancer~

tella, Inc. (Head office: Minato-ku, Tokyo; President & Representative Director: Yuichiro Yazaki) has signed a joint research agreement with School of Medicine, Keio University in January 2013. Based on this agreement, a Phase I clinical study has been performed for WTI peptide*1-pulsed dendritic cell vaccine Vaccell®*2 that is used in combination with an anticancer drug (gemcitabine hydrochloride) for treating advanced pancreatic cancer. The results of this clinical study were published in the academic publication of the Japanese Cancer Association “Cancer Science”*3.

Use of Vaccell® at tella’s contracted medical institutions was about 8,900 cases as of the end of 2014. Pancreatic cancer accounted for the largest number of cases at more than 1,700. Most of these were individuals who had already received chemotherapy or some other standard treatment and selected the dendritic cell vaccine Vaccell® because they had no other option.

At this clinical study, the first line therapy (the first treatment given) for individuals with pancreatic cancer who had not completed chemotherapy was gemcitabine hydrochloride, a chemotherapy drug combined with the dendritic cell vaccine Vaccell®. The safety and success rate of this treatment was assessed. In addition, the usefulness of immune monitoring was also checked.

For individuals where the pancreatic cancer had not spread to the liver, the administration of gemcitabine hydrochloride and the dendritic cell vaccine Vaccell® was confirmed to induce special T cells in antigen WTI. For first line therapy as well, the clinical study confirmed the efficacy of the induced immune response for cancer antigens. There have been clinical studies that involved using gemcitabine hydrochloride along with other chemotherapy drugs (such as S-1 and pacilitaxel), but there were reports of adverse events to the patients for all these clinical studies. This clinical study showed that using gemcitabine hydrochloride with the dendritic cell vaccine Vaccell® resulted in less adverse events to patients than combining this with other chemotherapy drugs.

For individuals where cancer had reached the liver, the research indicated the possibility of limited immune response inducing efficacy for patients with high levels of inflammation markers (CRP, IL6, IL8). These data indicate that there may be an improvement in the immune systems of individuals that had an anti-tumor immune response (WTI specific T cells) following the administration of Vaccell®. This may be very important data with respect to the future applications for Vaccell®.

tella will gather more scientific evidence about dendritic cell vaccine Vaccell® in order to develop and make available even better cell therapies.

This matter will have only a negligible effect on results of operations in fiscal 2015.
Note 1: WT1 peptides

WT1 peptides are a world-famous marker that occurs with almost all cancers as reported by Professor Haruo Sugiyama of the Graduate School of Osaka University among others. In a 2009 U.S. academic publication, WT1 peptides were selected as the highest priority cancer marker for treating cancer. tella holds the exclusive rights for using the WT1 peptide developed by Professor Sugiyama. By partially modifying a WT1 peptide with the proven potential for efficacy, there is a possibility of inducing an even more powerful cancer immunity. tella plans to obtain even stronger scientific evidence concerning the DC vaccine Vaccell® pulsed this WT1 peptide.

Note 2: Dendritic cell vaccine Vaccell®

This new cancer immunotherapy involves the production outside the patient’s body of a large volume of dendritic cells (a special type of cell that is a key regulator of the immune system and capable of activating lymphocytes that defend the body from foreign substances), which normally exist in only small quantities in the blood. These cells are then processed so that they recognize the patient’s cancerous tissues and substances (cancer antigens) produced artificially as a tumor marker. Next, the cells are returned to the patient’s body so that the characteristics of the cancer are transferred from the dendritic cells to lymphocytes. The lymphocytes can then attack only the cancer cells. tella’s goal is to receive approval of this vaccine as a regenerative drug for treating pancreatic cancer.

Note 3: Title of the thesis

Phase I pilot study of Wilms tumor gene 1 peptide-pulsed dendritic cell vaccination combined with gemcitabine in pancreatic cancer