Cell Genesys and Takeda Announce Global Alliance for the Development and Commercialization of GVAX Immunotherapy for Prostate Cancer

Cell Genesys and Takeda Pharmaceutical announced that they have formed a global alliance for the development and commercialization of GVAX immunotherapy for prostate cancer, Cell Genesys’ lead product candidate currently in Phase 3 clinical development.

Under the agreement, in exchange for exclusive worldwide commercial rights to GVAX immunotherapy for prostate cancer, Takeda will pay Cell Genesys an upfront payment of US$50 million and additional milestone payments totaling up to US$270 million relating to regulatory approval and commercialization of GVAX immunotherapy for prostate cancer in the United States, European Union and Japan. Takeda will pay Cell Genesys tiered, double-digit royalties based on net sales of GVAX immunotherapy for prostate cancer in the United States and flat double-digit royalties based on net sales of the product in all other regions. From this point forward, Takeda will pay for all external development costs associated with the ongoing Phase 3 clinical development of GVAX immunotherapy for prostate cancer and will also pay for all additional development costs and all commercialization costs. Cell Genesys will maintain responsibility for the worldwide manufacture and supply of the product and will retain rights to co-promote GVAX immunotherapy for prostate cancer in the United States.

Mr Stephen A. Sherwin, chairman and chief executive officer of Cell Genesys said, “We are very pleased to have entered into this agreement with Takeda for the development and commercialization of GVAX immunotherapy for prostate cancer and look forward to benefiting from Takeda’s impressive record of success as a global pharmaceutical business and clear commitment to become a leader in the field of oncology. In particular, we are very glad to have the opportunity to work with the company that pioneered the global development and commercialization of the world’s leading prostate cancer drug, Lupron®, and hope to build on that success with GVAX immunotherapy for prostate cancer, a potential new treatment option for men with this disease.”

Mr Yasuchika Hasegawa, president of Takeda said, “We are excited to have added GVAX immunotherapy for prostate cancer to our growing oncology pipeline and are eager to do all that we can to ensure its commercial success in the United States and globally. Our extensive experience in the prostate cancer market, coupled with our global infrastructure of development and marketing makes us well-suited to work in partnership with Cell Genesys in the effort to make GVAX immunotherapy for prostate cancer a reality for patients in need.”
GVAX immunotherapy for prostate cancer is currently being evaluated in two Phase 3 clinical trials, VITAL-1 and VITAL-2, in patients with advanced prostate cancer. The U.S. Food and Drug Administration have granted Cell Genesys Fast Track status for the GVAX prostate cancer program and both trials have completed Special Protocol Assessment agreements.

In 2007, the VITAL-1 trial completed enrollment with 626 patients and in January 2008, Cell Genesys announced that the Independent Data Monitoring Committee (IDMC) had completed a pre-planned interim analysis for VITAL-1 and recommended that the study continue.

The IDMC provided no information to the company other than the recommendation to continue the trial. The company currently estimates that there will be sufficient events to trigger the final analysis for VITAL-1 in the second half of 2009. Patients are continuing to be enrolled in the VITAL-2 trial at approximately 100 clinical trial sites located in North America and Europe. Cell Genesys is targeting the completion of enrollment for VITAL-2 with approximately 600 patients in the first half of 2009 and expects that there will be sufficient events to trigger the pre-planned interim analysis in the same time frame.

About GVAX Immunotherapy for Prostate Cancer
Cell Genesys’ GVAX cancer immunotherapies are whole-cell products that are designed to present the immune system with a broad spectrum of tumor antigens and stimulate an immune response against the patient’s tumor. GVAX immunotherapy for prostate cancer is comprised of two prostate tumor cell lines that have been modified to secrete GM-CSF (granulocyte-macrophage colony stimulating factor), an immune stimulatory hormone that plays a key role in stimulating the body’s immune response, and then irradiated for safety. GVAX for prostate cancer is being developed as a non patient-specific, “off-the-shelf” pharmaceutical product. The company is currently manufacturing the product in its bioreactor manufacturing facility in Hayward, California, a facility that is also capable of producing the product for commercialization.

About Cell Genesys
Cell Genesys is focused on the development and commercialization of novel biological therapies for patients with cancer. The company is currently pursuing two clinical stage product platforms—GVAX™ cancer immunotherapies and oncolytic virus therapies. Ongoing clinical trials include Phase 3 trials of GVAX immunotherapy for prostate cancer, Phase 2 trials of GVAX immunotherapies for pancreatic cancer and for leukemia, and a Phase 1 trial of CG0070 oncolytic virus therapy for bladder cancer. Cell Genesys is headquartered in South San Francisco, CA and has its principal manufacturing operation in Hayward, CA.

About Takeda
Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products.