



Gradalis Announces a Novel Combination Study of Vigil® EATC in Women with Advanced Ovarian Cancer

DALLAS, December 21, 2016 – Gradalis, Inc. a clinical stage cellular immunotherapy company, developing Vigil® Engineered Autologous Tumor Cell (EATC) therapy, today announced that it has entered into a collaboration agreement with Genentech, a member of the Roche Group to evaluate the combination of Gradalis' Vigil® EATC with Genentech's immune checkpoint, anti-PDL1 antibody atezolizumab (TECENTRIQ®). The planned Phase 2 clinical trial will be sponsored by Gradalis and evaluate the safety and anti-tumor activity of the combination in women with advanced ovarian cancer. Biomarkers will be used to measure the anti-tumor systemic immune response generated by Vigil alone, atezolizumab alone or the combination of the two agents.

"We are extremely pleased to embark on this immunotherapy combination study in ovarian cancer, an indication where we have seen encouraging early clinical results with Vigil® EATC alone and where we have an ongoing Phase 3 trial," said Sunil Joshi, President and Chief Executive Officer of Gradalis. "This trial complements and extends our ongoing efforts and hopefully will validate the biologic rationale and pre-clinical data in animals leading to further advances in the immunotherapy of ovarian cancer."

Vigil® EATC has demonstrated robust activation of the immune system as evidenced by previously published biomarker analysis in ovarian cancer. Atezolizumab is a monoclonal antibody designed to bind with programmed death-ligand 1 (PDL1), a protein that plays a role in preventing the body's immune system from fighting cancer. This investigational combination immunotherapy is designed to enhance the body's own immune defense against cancer by leveraging these two distinct mechanisms of action. Published pre-clinical evidence with similar agents provides a strong rationale for this clinical trial.

The study will begin in early 2017 and enroll up to 30 patients at multiple centers in the United States. Depending on the results observed, further development of the combination may be warranted.

About Vigil EATC:



Vigil is an investigational cellular immunotherapy technology that combines the concepts of genetic engineering with the science of immuno-oncology, to enable an immune response to cancer cells. A patient's tumor cells are engineered with a plasmid carrying the gene vector for shRNA Furin and GM-CSF to elicit a systemic T-cell directed immune response when administered to the patient through intradermal injections. By utilizing the patient's own tumor as the antigen source, Vigil EATC is designed to elicit an immune response that is specifically targeted and broadly relevant to each patient's unique tumor antigens. Vigil EATC is being studied in Ewing's sarcoma and ovarian cancer as a single agent, and in breast cancer, non-small cell lung cancer and melanoma in combination with PDL1 inhibitors. More information about these studies can be found on www.vigilclinicaltrials.com.

About Gradalis:



Gradalis

Gradalis is a fully integrated biotechnology company based in Dallas, Texas that focuses on the development, manufacturing, and commercialization of novel proprietary personalized cellular immunotherapies to treat cancer. Gradalis operates a cGMP manufacturing facility in Carrollton, Texas. For more information about Gradalis, Inc. please visit www.gradalisinc.com.

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