Gradalis to Host Virtual KOL Discussion on the Vigil® Platform Entering Phase 2 for Platinum-Sensitive Recurrent Ovarian Cancer on October 25, 2023

DALLAS, Oct. 18, 2023 (GLOBE NEWSWIRE) -- Gradalis, Inc. announced that it will host a virtual KOL discussion on the Vigil® platform entering Phase 2 for platinum-sensitive recurrent ovarian cancer on Wednesday, October 25, 2023 at 11:00am ET. To register for the event, click here.

The event will feature Rodney P. Rocconi, M.D., Director, Cancer Center & Research Institute and Professor, Gynecologic Oncology at the University of Mississippi Medical Center, who will discuss the unmet medical need and current treatment landscape for patients suffering from ovarian cancer, along with the potential for Vigil, a fully personalized, patient-specific cancer immunotherapy with applications across multiple solid tumor types including ovarian cancer.

John Nemunaitis, M.D., Gradalis' Chief Scientific Officer, will present on the Vigil mechanism, highlighting how it uses the patient's own tumor as the antigen source. Vigil is designed to elicit an immune response that is specifically targeted to each patient's unique "clonal" tumor neoantigens. John will share published research showing that targeting clonal neoantigens is critical in generating a durable clinical response and that Vigil is designed to expand the population of effector cells targeting clonal neoantigens.

A live question and answer session will follow the formal presentations.

About Rodney P. Rocconi, M.D.
Dr. Rocconi currently serves as Director, Cancer Center & Research Institute and Professor, Gynecologic Oncology at the University of Mississippi Medical Center. He has a productive research career credited with over 200 presentations at national meetings and over 120 publications. His research interests include genetic/molecular determinants of racial healthcare disparities in gynecologic malignancies as well as understanding the molecular mechanisms of chemoresistance in ovarian cancer. His research program has been supported by numerous NIH/NCI, DOD, PCORI, and foundation grants. He has been recognized for his work as a recipient of the Gynecologic Cancer Foundation Ovarian Cancer Research Award, the Gynecologic Oncology Group Young Investigator Research Award, and an invited Associate Member of the NCI Early Detection Research Network.

About John Nemunaitis, M.D.
Dr. Nemunaitis is the co-founder and Chief Scientific Officer of Gradalis, Inc. He earned his medical degree at Case Western Reserve University in Cleveland, Ohio, followed by residency training at Boston City Hospital in Massachusetts. He also completed a fellowship in oncology/hematology at the University of Washington School of Medicine's Fred Hutchinson Cancer Research Center in Seattle, Washington where he worked closely with E. Donnall Thomas, Nobel Prize laureate. He founded the Mary Crowley Cancer Research Translational Center in Dallas, Texas and was part of the CPRIT initiating team as first Chairman of the Scientific and Prevention Advisory Council. His specialties include general oncology, clinical trial development, genetic signal mapping, and precision therapy. Dr. Nemunaitis has published 499

peer-reviewed manuscripts and book chapters and has overseen the management of over 600 clinical trials involving several thousand cancer patients.

About Ovarian Cancer
Ovarian cancer patients are composed of two groups with differing levels of DNA repair capability, each representing about 50% of ovarian cancer patients: HRP profile – good DNA repair; HRD/BRCA-mutant profile – poor DNA repair. HRP tumors are better able to repair DNA and the clonal neoantigens are better preserved on HRP type tumors. Patients with the HRD/BRCA-mutant profile have an impaired DNA repair mechanism that is associated with higher subclonal neoantigen profiles compared to the HRP profile. As a result, HRP patients' tumors should respond better to Vigil therapy than HRD/BRCA-mutant patients. Results of Vigil in a Phase 2b study in HRP ovarian cancer patients are consistent with these findings. Importantly in patients with tumors of the HRP type, there is a high unmet medical need due to the limited effectiveness of chemotherapy and PARP therapies.

About Vigil
Vigil® is a novel, triple function immunotherapy platform that modifies a patient's tumor by using bi-shRNA to reduce furin, an enzyme which facilitates immunosuppressive TGF beta protein production, and to maximize DNA expression of GM-CSF, which stimulates the immune system and attracts key immune system effector cells, including T cells. By utilizing the patient's own tumor as the antigen source, Vigil is designed to elicit an immune response that is specifically targeted and broadly relevant to each patient's unique "clonal" tumor neoantigens. Vigil therapy has been well tolerated in Phase 1, 2a and 2b clinical studies.

In VITAL, a multicenter, randomized, double-blind, placebo-controlled Phase 2b trial in Stage III/IV newly diagnosed, frontline ovarian cancer patients, Vigil showed a positive trend in the primary endpoint of recurrence free survival (RFS) in the overall population and a statistically significant improvement in the secondary endpoint of RFS and overall survival (OS), with a median survival time of three years to date, in patients with the BRCAwt molecular profile. Importantly in patients with tumors of the HRP molecular profile where there is a high unmet medical need, a statistically significant improvement was seen in RFS and OS.

Additionally, Phase 1 results in an "all-comer" clinical trial have shown positive signals of activity in 19 different tumor types and some patients treated with Vigil remain in the study 48 months later. Vigil has also demonstrated safety and benefit in two separate studies when administered concurrently or in sequence prior to treatment with check point inhibitor therapy. These results support Vigil induced systemic induction of effector cells with capacity to specifically attack the patient's own cancer after Vigil treatment. The company is preparing to initiate a Phase 2 clinical study in platinum-sensitive recurrent ovarian cancer patients with the HRP profile.

About Gradalis, Inc.
Founded in 2006, Gradalis is a privately held, clinical stage biotechnology company developing a personalized immunotherapy called Vigil, that has been tested in multiple studies in ovarian and other cancer tumor types. Vigil is the first cellular immunotherapy to demonstrate longer-term

overall survival benefits in a randomized controlled trial of patients with solid tumors. The results of the company's Phase 2b study have been published in *Lancet Oncology* and presented at the American Society of Clinical Oncology. Vigil has shown positive results in combination with checkpoint inhibitors.

Gradalis' Vigil platform uses the patient's immune system to target the entire tumor. Based on multiple clinical studies, Gradalis has developed an oncology platform that is designed to decloak the full repertoire of a patient's tumor antigens, including all clonal neoantigens, reactivate the immune system, and summon key effector cells to deliver a durable clinical response. When combined, these are a powerful Trifecta of anticancer activities, potentially eliminating even the elusive metastatic cells, and as shown in Phase 2 clinical studies in ovarian cancer, a potential gamechanger in oncology. Our clinical trials have also demonstrated that Gradalis' platform is better tolerated compared to standard cancer treatments since Vigil uses the patient's immune system operating within its natural state of balance rather than in an artificial overdrive as with some technologies. Vigil utilizes proprietary bi-shRNA technology that has been proven to silence multiple genes in a variety of cancers and has the potential to be used in other diseases.

Forward-Looking Statements
This press release contains forward-looking statements, including, without limitation, statements regarding the success, cost, and timing of our product development activities and clinical trials, our plans to research, develop, and commercialize our product candidates, and our plans to submit regulatory filings and obtain regulatory approval of our product candidates. These forward-looking statements are based on Gradalis' current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements include but are not limited to: (a) the timing, costs, and outcomes of our clinical trials and preclinical studies, (b) the timing and likelihood of regulatory filings and approvals for our product candidates, and (c) the potential market size for our product candidates. These forward-looking statements speak only as of the date made and, other than as required by law, we undertake no obligation to publicly update or revise any forward-looking statements. This press release does not constitute an offer to sell, or a solicitation of an offer to buy, any securities.

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