Gradalis to Host Key Opinion Leader Webinar on Unmet Medical Needs in Ovarian Cancer and the Company's Immuno-Oncology Treatment, Vigil®

-Webinar to feature presentations from Rodney Rocconi, M.D. and John Nemunaitis, M.D., on Monday, October 3rd at 1:00 p.m. ET

Dallas, Texas, September 28, 2022 – Gradalis, a privately-held, late-stage biotechnology company developing immunotherapies for ovarian and other cancers, today announced that it will host a key opinion leader (KOL) webinar on the current treatment landscape for ovarian cancer and Vigil®, the company's fully personalized, patient-specific cancer immunotherapy, on Monday, October 3, 2022 at 1:00 p.m. ET.

Rodney Rocconi, M.D., FACOG, Professor, Obstetrics and Gynecology at University of Alabama at Birmingham, will discuss the current treatments for patients with ovarian cancer and the need for new therapies. Gradalis' Chief Scientific Officer John Nemunaitis, M.D., will review results from VITAL, a Phase 2b clinical trial evaluating Vigil as maintenance therapy for ovarian cancer patients and the clinical development path forward. Gradalis is developing Vigil, a novel, personalized cellular immunotherapy platform that is designed to decloak the full repertoire of a patient's tumor neoantigens, reactivate the immune system, and summon key effector cells to deliver a durable clinical benefit. Gradalis is preparing to initiate a Phase 3 trial designed for product registration of Vigil in patients with ovarian cancer.

A live Q&A session will follow the formal presentations. To register for the event, please click here.

Rodney Rocconi, **M.D., FACOG,** currently serves dual roles in a partnership between the University at Alabama at Birmingham (UAB) and Infirmary Cancer Care (ICC) in Mobile, Alabama. In addition to being Professor of Gynecologic Oncology at UAB, he holds leadership positions of Associate Director and Director of Research at ICC in Mobile, Alabama. He has presented research at over 200 national meetings and published over 120 peer-reviewed manuscripts. 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. Dr. Rocconi has served as principal investigator in over 60 clinical trials with multiple early phase 1/2 investigator-initiated studies. 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.

John Nemunaitis, M.D., is Gradalis Chief Scientific Officer and co-founder. Over 30 years, he has led teams to translate innovative science into cancer treatment therapies at Gradalis, the Mary Crowley Foundation, and the Fred Hutchinson Cancer Center. A recognized expert in his field, John has been involved in the design and execution of over 600 clinical trials across all of the major tumor types and overseen the management of over 6500 patients in those studies. He

has been an author in 493 peer-reviewed publications and 27 patents issued for targeted therapeutics. He has been involved in 30 new product IND's (15 first in human), served on the FDA's Recombinant DNA Advisory Committee, and has participated in 72 government regulatory presentations.

About Gradalis, Inc.
Founded in 2003, Gradalis is a privately held, late-stage clinical biotechnology company developing a personalized immunotherapy called Vigil, that has been tested in multiple studies in ovarian and other cancer tumor types. Based on its Phase 2b clinical trial results, the company is preparing to initiate a Phase 3 trial designed for product registration of Vigil in patients with ovarian cancer. Vigil is the first cellular immunotherapy to demonstrate survival benefits in a randomized controlled trial of patients with solid tumors. The results of the company's Phase 2b trial have been published in *Lancet Oncology* and presented at the American Society of Clinical Oncology. Vigil is being studied in other cancer types and 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 neoantigens, reactivate the immune system, and summon key effector cells to deliver a durable clinical response. When combined, these are a powerful Trifecta of anti-cancer activities, potentially eliminating even the elusive metastatic cells, and as shown in Phase 2 clinical studies in ovarian cancer, a potential gamechanger in oncology. Clinical trials of Vigil 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.

About Vigil
Vigil® is a novel, personalized immunotherapy platform designed to achieve a Trifecta of immune anticancer activity using a unique bi-shRNA DNA based plasmid and the patient's own tumor tissue. The Trifecta of systemic activity involves knock down of TGFβ1 and TGFβ2 which function as tumor suppressor cytokines, increased GM-CSF expression to enhance local immune function and presentation of the patient's clonal neoantigen epitopes via use of autologous cancer tissue. 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 (NCT02346747), Vigil showed a positive trend in the primary endpoint of recurrence free survival (RFS) in the overall population and a statistically significant improvement in RFS and overall survival (OS), with a median time of three years to date, in a pre-planned subgroup analysis of Stage III/IV newly diagnosed ovarian cancer patients with the BRCAwt molecular

profile. In patients with tumors of the HRP type, significant additional improvement was seen in RFS and OS.

Additionally, Phase 1 results in a “basket” clinical trial have shown positive signals of activity in 19 tumor types and some patients treated with Vigil remain in the trial 48 months later. The company is preparing to initiate a clinical trial intended for product registration in patients with the HRP subtype ovarian cancer.

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.

Gradalis Contact
Mark Early
(214) 442-8161
mearly@gradalisinc.com

LifeSci Advisors Contact
Joyce Allaire
+1 (617) 435-6602
jallaire@lifesciadvisors.com