Gradalis to Participate in the Cantor Fitzgerald Future of Oncology Symposium

DALLAS, March 29, 2023 (GLOBE NEWSWIRE) -- Gradalis, Inc., a privately held, late-stage clinical biotechnology company developing a personalized immunotherapy called Vigil® for patients with ovarian and other cancer tumor types, today announced that Steven Engle, Chief Executive Officer, will participate in a fireside chat at the Cantor Fitzgerald Future of Oncology Symposium, being held virtually from April 3 – 5, 2023.

Format: Virtual Fireside Chat
Date: Monday, April 3, 2023
Time: 3:00 PM ET

A live webcast and archived replay of the fireside chat will be available to registered attendees of the symposium and can be accessed here or through the symposium website.

About Gradalis, Inc.
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. The company has received clearance from the FDA to initiate a Phase 3 trial designed for product registration of Vigil in patients with advanced ovarian cancer. Vigil is the first cellular immunotherapy to demonstrate survival benefits in a randomized controlled trial of ovarian cancer patients. 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.

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

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