Galera Therapeutics Raises $150 Million for GC4419 Phase 3 Trial and Pre-Commercialization Activities in Lead Indication

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Pivotal trial of GC4419 for the treatment of severe oral mucositis in patients with head and neck cancer expected to initiate in fourth quarter 2018

MALVERN, Penn. — September 19, 2018— Galera Therapeutics, Inc., a clinical-stage biotechnology company focused on the development of drugs targeting oxygen metabolic pathways with the potential to transform cancer radiotherapy, today announced it has secured $150 million in a joint, oversubscribed Series C financing and royalty purchase agreement. The financing was led by new investor Clarus, with participation from additional new investors Adage Capital Management, HBM Healthcare Investments, Nan Fung Life Sciences, RA Capital, Rock Springs Capital and Tekla Capital Management LLC. Existing investors Correlation Ventures, Galera Angels, New Enterprise Associates, Novartis Venture Fund, Novo Ventures and Sofinnova Ventures also participated. In addition, Emmett T. Cunningham, Jr., M.D., Ph.D., MPH, Managing Director at Clarus, will join Galera's Board of Directors.

The financing includes a $70 million equity raise and an $80 million royalty financing payable from future sales. Per the terms of the royalty purchase agreement, Clarus will receive single-digit future commercial royalties from the sales of GC4419 and a related pipeline asset until the total royalty amount achieves an undisclosed multiple of the initial $80 million, upon which the royalty terminates.

Galera plans to use the proceeds of the combined equity and royalty financings to advance the clinical development of GC4419 into and through a pivotal Phase 3 clinical trial for the treatment of severe oral mucositis (SOM) in patients with head and neck cancer, its lead indication. SOM is one of the most debilitating side effects of radiotherapy, and there are currently no effective therapies to prevent or mitigate it. In a Phase 2b clinical trial, GC4419 demonstrated reductions in the incidence and duration of radiation-induced SOM in patients with locally advanced head and neck cancer.

"This significant raise further validates the dramatic and meaningful results of our randomized Phase 2b clinical trial and the potential of GC4419 to revolutionize radiotherapy. We are grateful for the robust support from existing and new investors as we prepare to advance GC4419 into a pivotal trial for SOM in head and neck cancer patients in the fourth quarter of this year," said Mel Sorensen, M.D., President and CEO of Galera. "The funds provide Galera with ample financial resources to complete the Phase 3 clinical trial, begin commercial planning activities and further explore the potential of GC4419 beyond SOM. We look forward to initiating a supportive care trial of GC4419 in radiation-induced esophagitis and a therapeutic trial in a second cancer indication, as well as continuing to evaluate the safety and anti-tumor effect of GC4419 in our ongoing Phase 1/2 pancreatic cancer clinical trial."

"Galera has generated robust, randomized Phase 2b data supporting the efficacy and safety profile of GC4419. These data, along with Breakthrough and Fast Track designations from the U.S. Food and Drug Administration (FDA), support the promise of GC4419 to transform how radiotherapy is used to treat patients with head and neck malignancies," said Dr. Cunningham. "With its highly differentiated scientific approach and its potential in a number of indications, GC4419 is well-positioned to address serious unmet medical needs. We're pleased to support Galera as the company moves closer to potentially bringing GC4419 to head and neck cancer patients with SOM who need a new treatment option."

About GC4419

GC4419 is a highly selective and potent small molecule dismutase mimetic that closely mimics the activity of human superoxide dismutase enzymes. GC4419 works to reduce elevated levels of superoxide caused by radiation therapy by rapidly converting superoxide to hydrogen peroxide and oxygen. Left untreated, elevated superoxide can damage noncancerous tissues and lead to debilitating side effects, including oral mucositis (OM), which can limit the anti-tumor efficacy of radiation therapy. Conversion of elevated superoxide to hydrogen peroxide, which is selectively more toxic to cancer cells, can also enhance the effect of radiation on tumors, particularly with stereotactic body radiation therapy (SBRT), which produces high levels of superoxide.

GC4419 has been studied in patients with head and neck cancer, GC4419's lead indication, for its ability to reduce the incidence and duration of radiation-induced severe oral mucositis. Results from Galera's 223-patient, double blind, randomized, placebo-controlled Phase 2b clinical trial demonstrated GC4419's ability to dramatically reduce the duration of SOM from 19 days to 1.5 days (92 percent), the incidence of SOM through completion of radiation by 34 percent and the severity of patients' OM by 47 percent, while demonstrating acceptable safety when added to a standard radiotherapy regimen. GC4419 is currently being studied in combination with SBRT for its anti-tumor effect in a Phase 1/2 trial of patients with locally advanced pancreatic cancer. In addition, in multiple preclinical studies, GC4419 demonstrated an increased tumor response to radiation therapy while preventing toxicity in normal tissue.

The FDA granted Breakthrough Therapy designation to GC4419 for the reduction of the duration, incidence and severity of SOM induced by radiation therapy with or without systemic therapy. The FDA also granted Fast Track designation to GC4419 for the reduction of the severity and incidence of radiation and chemotherapy-induced OM.

About Galera Therapeutics

Galera Therapeutics, Inc. is a privately held, clinical-stage biotechnology company focused on discovering and developing novel therapeutics targeting oxygen metabolic pathways with the potential to transform how radiation therapy is used in patients with cancer. Galera's lead product candidate is GC4419, a highly selective and potent small molecule superoxide dismutase enzyme mimetic that rapidly converts superoxide to hydrogen peroxide and oxygen. GC4419 achieved positive results in a Phase 2b clinical trial, which demonstrated its ability to reduce the incidence and duration of radiation-induced severe oral mucositis in patients with head and neck cancer, its lead indication. The U.S. Food and Drug Administration granted Fast Track and Breakthrough Therapy designations to GC4419. Galera is headquartered in Malvern, PA. For more information, visit www.galeratx.com.

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