
xCures Collaborates with Oncoceutics to Implement the Company's Intermediate Size Expanded Access Protocol for ONC201 in H3 K27M-mutant gliomas

March 8, 2019 – xCures and Cancer Commons are pleased to announce a collaboration with Oncoceutics to implement the Expanded Access policy of the company. Part of this Expanded Access program is an intermediate size Expanded Access protocol for ONC201 in patients with H3 K27M-mutant glioma entitled “ONC018: Expanded Access to ONC201 for Patients with H3 K27M-mutant and/or Midline High Grade Gliomas” that was recently accepted by the U.S. Food and Drug Administration (FDA).

The H3 K27M mutation has been identified as an important prognostic indicator in aggressive midline gliomas that involve specific parts of the brain, including the thalamus, pons, or spinal cord. In 2016, the World Health Organization categorized any midline brain tumor that contains the H3 K27M mutation as the highest grade (IV) because the mutation confers such a poor prognosis. Beyond palliative radiation, no medical therapy has been shown to provide clinical benefit for patients with this mutation in their tumor. Pediatric patients are particularly impacted by this mutation, especially those with DIPG where 70-80% of the patients have the mutation.

[ONC201](#) is an investigational, novel small molecule with a unique and novel mechanism of action that is currently under clinical investigation in several Phase II trials. Ongoing clinical trials with ONC201 include trials in adult and pediatric patients with high-grade gliomas that harbor an H3 K27M mutation that can be identified by immunohistochemistry or gene sequencing (e.g. FoundationOne CDx). H3 K27M-mutant glioma is a molecularly-defined disease with a dismal prognosis. Oncoceutics' clinical trials are being carried out at numerous leading cancer centers across the United States, including Massachusetts General Hospital, Dana Farber Cancer Institute, NYU Langone, MD Anderson Cancer Center, Levine Cancer Institute, Miami Cancer Institute, University of California San Francisco, Emory University and the University of Michigan. In addition, several other leading cancer centers across the United States are in the process of joining the program.

Given the rare incidence and prevalence of patients suffering from H3 K27M-mutant gliomas and the severe clinical symptoms that these patients often sustain, disabling them from travel to cancer centers, the options to enroll patients on clinical studies are limited.

The intermediate-size expanded access program is intended to give options to patients that do not qualify for currently available therapies, allowing the company to make the investigational drug therapy available to patients that may be eligible for the Expanded Access program. xCures and Cancer Commons will work together with Oncoceutics in those cases where patients cannot participate in ongoing clinical research programs. The collaborators will work to facilitate the process in close cooperation with the patient's treating physicians and hospital system.

“We are pleased to see rapid progress in the development of ONC201 in H3 K27M-mutant gliomas as well as those with midline high-grade gliomas, a serious disease that principally has no satisfactory standard of care,” said William Hoos, Chief Operating Officer, xCures. “We believe novel access approaches like this Intermediate Size Expanded Access Protocol, **performed in a continuous learning system capable of generating regulatory grade data**, are important to speed up progress for brain cancer patients who currently do not have effective treatment or trial options. We appreciate the support The Musella Foundation, The Cure Starts Now Foundation and Michael Mosier Defeat DIPG Foundation.”

About xCures, Inc.

xCures is developing an AI-based methodology and platform to run 'Virtual Trials', which continuously learn from the clinical experiences of all patients, on all treatments, all the time. Each patient's treatment regimen is adaptively planned by a 'Virtual Tumor Board' to optimize their individual outcome, and these plans are coordinated across the whole patient population to maximize collective learning. Visit xcures.com for more information.

About The Musella Foundation

The Musella Foundation For Brain Tumor Research & Information, Inc is a 501(C)3 nonprofit public charity dedicated to helping brain tumor patients through emotional and financial support, education, advocacy and raising money for brain tumor research. Visit virtualtrials.com for more information.

About Cancer Commons

Cancer Commons is a nonprofit collaborative of patients, physicians, and scientists, dedicated to improving patient outcomes by tightly coupling clinical research and care. We arm patients and their physicians with the knowledge they need to achieve the best possible outcomes, help them access the relevant treatments and trials, and track their results to continuously learn. Visit cancercommons.org for more information.

About The Cure Starts Now Foundation

The Cure Starts Now Foundation is a 501(c)3 nonprofit organization with international chapters in nearly 40 locations around the world. It has funded universal cancer cure strategies starting with cancers such as DIPG and organizes the biennial International DIPG Symposium showcasing innovative research methods. You can learn more at www.thecurestartsnow.org.

About Michael Mosier Defeat DIPG Foundation

Michael Mosier Defeat DIPG Foundation is committed to finding a cure for brainstem tumors known as diffuse intrinsic pontine gliomas (DIPG). Nearly every day one child in the United States is diagnosed with DIPG and another child dies from it. The Foundation seeks to make a difference and defeat DIPG both by raising awareness of DIPG and by providing funding for research into effective treatments for DIPG. Visit defeatdipg.org for more information.

About Oncoceutics, Inc.

Oncoceutics, Inc. is a clinical-stage drug discovery and development company with a novel class of compounds, called "imipridones," that selectively target G protein-coupled receptors for oncology. The first lead compound to emerge from this program is [ONC201](#), an orally active small molecule DRD2 antagonist. The company is supported by grants from NCI, FDA, Musella Foundation, XCures, Cancer Commons, and a series of private and public partnerships. Visit [Oncoceutics](#) or contact Press@oncoceutics.com for more information.