

Shuttle Pharma Ready to Enroll Patients in Phase 2 Clinical Trial of Ropidoxuridine for Treatment of Patients with Glioblastoma

GAITHERSBURG, Md., Aug. 14, 2024 — Shuttle Pharmaceuticals Holdings, Inc. (Nasdaq: SHPH) (“Shuttle Pharma”), a discovery and development stage specialty pharmaceutical company focused on improving outcomes for cancer patients treated with radiation therapy (RT), announced today it has entered into agreements with two of the six site locations to administer the Phase 2 clinical trial of Ropidoxuridine for the treatment of patients with glioblastoma. Site initiation visits have been completed for two sites. The trial is now open to enroll patients in the clinical trial.

Ropidoxuridine (IPdR) is Shuttle Pharma’s lead candidate radiation sensitizer for use in combination with RT to treat brain tumors (glioblastoma), a deadly malignancy of the brain with no known cure. Shuttle has received Orphan Drug Designation from the FDA, providing potential marketing exclusivity upon first FDA approval for the disease.

The Phase 2 clinical trial will be conducted on patients with the most aggressive brain tumors out there - IDH wild-type, methylation negative glioblastoma. Presently, radiation is the only approved standard of care for this particular group of patients, with more than half of the patients surviving for less than 12 months after diagnosis. Shuttle Pharma’s Phase 2 clinical trial will consist initially of 40 patients randomized into two different doses (20 @ 1,200 mg/day and 20 @ 960 mg/day) to determine an optimal dose. Once the Company determines the optimal dose, it will then add an additional 14 patients on the optimal dosage allowing for the achievement of statistical significance with the end point being that of survival as compared to historical controls. The Company expects the trial to be completed over a period of 18 to 24 months.

“We are pleased to be working with highly talented teams at academic medical centers on our Phase 2 trial of Ropidoxuridine for the treatment of patients with glioblastoma,” commented Shuttle Pharma’s Chairman and CEO, Anatoly Dritschilo, M.D. “The results of this trial will be important to the cancer community as we look for ways to leverage radiation sensitizers to increase cancer cure rates, prolong patient survival and improve quality of life for patients suffering from glioblastoma.”

Shuttle Pharma expects the Phase 2 clinical trial will be carried out at six site locations, with all sites anticipated to be treating patients in the coming months.

“We have carefully selected six universities and hospitals that are most likely to treat IDH wild-type, methylation negative glioblastoma patients which should allow for more rapid enrollment of the Phase 2 trial,” added Dr. Tyvin Rich, Chief Medical Officer of Shuttle Pharma and Professor Emeritus of Radiation Oncology, University of Virginia School of Medicine.

An estimated 800,000 patients in the US are treated with radiation therapy for their cancers yearly. According to the American Cancer Society and the American Society of Radiation Oncologists, about 50% are treated for curative purposes and the balance for therapeutic care. The market opportunity for radiation sensitizers lies with the 400,000 patients treated for curative purposes, with this number expected to grow by more than 22% over the next five years.

More information about the Phase 2 study (NCT06359379) can be found at www.clinicaltrials.gov.

About Shuttle Pharmaceuticals

Founded in 2012 by faculty members of the Georgetown University Medical Center, Shuttle Pharma is a discovery and development stage specialty pharmaceutical company focused on improving the outcomes for cancer patients treated with radiation therapy (RT). Our mission is to improve the lives of cancer patients by developing therapies that are designed to maximize the effectiveness of RT while limiting the side effects of radiation in cancer treatment. Although RT is a proven modality for treating cancers, by developing radiation sensitizers, we aim to increase cancer cure rates, prolong patient survival and improve quality of life when used as a primary treatment or in combination with surgery, chemotherapy and immunotherapy. For more information, please visit our website at www.shuttlepharma.com.

Safe Harbor Statement

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements." These statements include, but are not limited to, statements concerning the development of our company. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including factors discussed in the "Risk Factors" section of Shuttle Pharma's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 20, 2024, as well other SEC filings. Any forward-looking statements contained in this press release speak only as of the date hereof and, except as required by federal securities laws, Shuttle Pharmaceuticals specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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