Shuttle Pharmaceuticals Receives FDA Approval to Proceed with Phase II Clinical Trial of Ropidoxuridine for Treatment of Patients with Glioblastoma

ROCKVILLE, Md., Jan. 8, 2024 — Shuttle Pharmaceuticals Holdings, Inc. (Nasdaq: SHPH) ("Shuttle Pharma") today announced they have received the 'Safe to Proceed' letter from the U.S. Food and Drug Administration (FDA) for the Company's investigational new drug (IND) application for its Phase II study of Ropidoxuridine (IPdR) as a radiation sensitizing agent during radiotherapy in patients with newly diagnosed IDH-wildtype glioblastoma with unmethylated MGMT promoter. Receipt of the letter allows Shuttle to commence the Phase II study.

Shuttle Pharma is currently finalizing site enrollment with 'first patient, first dose' expected in the coming months. Ropidoxuridine is Shuttle Pharma's lead radiation sensitizer candidate for use in combination with radiation therapy (RT) to treat glioblastoma, a deadly malignancy of the brain with no known cure.

"We are excited to have been granted approval to commence Ropidoxuridine's Phase II clinical trial following the receipt of the FDA's 'Safe to Proceed' letter," stated Shuttle Pharma's Chairman and CEO, Anatoly Dritschilo, M.D. "Radiation therapy is a proven modality for treating cancers. However, there is a significant need in the market to make radiation more effective. The results of this Phase II clinical trial will be important as we look to leverage radiation sensitizers to increase cancer cure rates, prolong patient survival and improve quality of life for patients suffering from glioblastoma."

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.

Shuttle Pharma has received Orphan Drug Designation from the FDA, providing potential marketing exclusivity upon first FDA approval for the disease.

About Shuttle Pharmaceuticals

Founded in 2012 by faculty members of the Georgetown University Medical Center, Shuttle Pharmaceuticals 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, 2022, filed with the SEC on March 15, 2023, and its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023, June 30, 2023 and September 30, 2023, filed with the SEC on May 25, 2023, August 14, 2023 and November 13, 2023, respectively, 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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