

## Shuttle Pharmaceuticals Engages Theradex Oncology in Preparation for Clinical Study

ROCKVILLE, Md., Nov. 3, 2022 — Shuttle Pharmaceuticals Holdings, Inc. (Nasdaq: SHPH), a discovery and development stage specialty pharmaceutical company focused on improving the outcomes of cancer patients treated with radiation therapy (RT) while reducing its side effects, today announced it has engaged Theradex Oncology, a leading clinical research organization (“CRO”), to help prepare for its upcoming clinical study of Ropidoxuridine.



Theradex Oncology will assist the Company in meetings with the FDA and preparation of the IND (Investigational New Drug) application for the planned Phase II clinical study of Ropidoxuridine and radiation therapy. Shuttle anticipates final IND application submission to the FDA in the second quarter of 2023.

“We are excited to advance our regulatory work with Theradex as we accelerate the development of Ropidoxuridine for the treatment of brain tumors,” said Dr. Anatoly Dritschilo, Chief Executive Officer of Shuttle Pharmaceuticals. “Theradex’s expertise in regulatory and statistical design is particularly helpful in meeting FDA requirements and providing guidance in study design and statistical support for the clinical trial.”

Ropidoxuridine, Shuttle’s lead clinical stage product candidate, is an orally available halogenated pyrimidine (5-iodo-2-pyrimidinone-2-deoxyribose) with strong cancer radiation sensitizing properties. As a prodrug, it becomes active after it is metabolized to IUdR, a halogenated pyrimidine that is incorporated into DNA by rapidly growing cancer cells. Cells that incorporate IUdR into their DNA become more sensitive to the effects of RT.

The reported Phase I clinical trial of Ropidoxuridine and RT supports the proposed Phase II clinical trial, through which the FDA will determine efficacy in treating brain tumors

(glioblastoma). The FDA has granted approval of the Company's application for orphan-drug designation for Ropidoxuridine for the treatment of glioblastoma.

Dr. Dritschilo added, "Radiation therapy is a proven modality for cancer treatment. However, by developing radiation sensitizers, we aim to increase cancer cure rates, prolong patient survival and improve quality of life when radiation is used as a primary treatment or in combination with surgery, chemotherapy and immunotherapy."

Theradex Oncology has provided full oncology clinical trial services in the US and Europe for over three decades. Meg Valnoski, president of Theradex, will be directly involved in the regulatory support provided to Shuttle Pharmaceuticals, working closely with a diverse team of experts to ensure the successful execution of clinical trials.

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, and this number is expected to grow by more than 22% over the next five years. Based on a rough estimate of a course of radiation sensitizing brand drug therapy (off label at this time) of \$12,000 per patient, the market size is estimated to be in excess of \$4.0 billion.

### **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](http://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 forward-looking statements include, but are not limited to, statements concerning the development of our company, including prospects related to our engagement of Theradex Oncology to prepare for and conduct our Phase II clinical trials for Ropidoxuridine. 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 our IPO prospectus filed with the SEC on August 31, 2022. 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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