

Shuttle Pharmaceuticals Provides Third Quarter 2022 Corporate Update

ROCKVILLE, Md., Nov. 15, 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), today provided a corporate update in connection with the filing of its Quarterly Report on Form 10-Q for the quarter ended September 30, 2022.



Recent Highlights

- Completed an initial public offering (“IPO”) raising gross proceeds of \$10.0 million with listing of its common shares on the Nasdaq Capital Market.
- Closed on the overallotment option resulting in additional gross proceeds of \$1.5 million.
- Entered into an agreement with TCG GreenChem, Inc. to manufacture Ropidoxuridine, the Company’s lead clinical sensitizer drug candidate, for use in formulating the drug product for testing in clinical trials of Ropidoxuridine and RT of cancers.
- Engaged Theradex Oncology, a leading clinical research organization, to help prepare for its upcoming clinical study of Ropidoxuridine.
- Awarded patents in the U.S. and Hong Kong for its radiation sensitizing HDAC inhibitor technology platform.
- Appointed Dr. Bette Jacobs to its Board of Directors as an independent director.

“The past few months have been exciting for Shuttle as we completed our IPO and made progress on a number of important activities in the advancement of our lead clinical sensitizer drug candidate, Ropidoxuridine, aimed at improving the outcomes of cancer treatment through radiation therapy while reducing its side effects,” commented Shuttle Pharma’s Chairman and CEO, Anatoly Dritschilo, M.D. “With a Phase I clinical trial of

Ropidoxuridine and radiation therapy completed in patients with advanced colorectal cancers to establish the maximum tolerated dose and levels of drug availability in the blood after oral administration, our next steps are to perform a Phase II clinical trial in brain cancer patients undergoing radiation therapy for glioblastoma. We are preparing the Investigational New Drug application for the study with an expectation of final submission to the FDA in the second quarter of 2023. I look forward to continued progress in the quarters ahead as we look to execute on our mission to deliver innovative new treatments to thousands of patients who currently lack effective therapies.”

The Ropidoxuridine Opportunity

Radiation therapy is a proven modality for cancer treatment. By developing radiation sensitizers, Shuttle Pharma aims to increase 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.

Modern oncology incorporates multi-modality strategies that use combinations of surgery, chemo or immunotherapy, and radiation to treat cancers. Radiation therapy requires delivery and shaping of high doses of radiation energy to tumors to kill or slow the growth of cancer cells by damaging their cellular DNA. State-of-the-art technologies to deliver the radiation doses include image guided treatments with linear accelerators and particle radiation with protons. However, radiation therapy of adjacent healthy tissues can lead to injuries of normal organs. The addition of radiation sensitizers allows preferential increased killing of cancer cells.

Currently, there is only one drug on the market approved by the FDA as a radiation sensitizer. However, that drug has a host of side effects that limit its utility. Other drugs are used “off label” by radiation oncologists, but these often have additional side effects. There is an urgent need for an effective radiation sensitizer with low toxicity for use in combination with radiation therapy. The Company’s lead candidate, Ropidoxuridine, is an orally available prodrug, that once ingested, metabolizes into iododeoxyuridine, a pyrimidine analog, that has been recognized as a radiosensitizing agent since the 1960’s.

Various sources have estimated that more than 800,000 patients are treated annually in the U.S. with radiation therapy for their cancers. About 50% are treated for curative purposes and the balance for palliative care. The market opportunity for radiation sensitizers lies with the 400,000 patients treated with curative intent. Based on a rough estimate of a course of radiation sensitizing brand drug therapy, which are used off label at this time, the potential market size is estimated to be in excess of \$4.0 billion annually.

Manufacturing Agreement

In September 2022, the Company announced it entered into an agreement with TCG

GreenChem, Inc. to manufacture Ropidoxuridine, the Company's lead clinical sensitizer drug candidate, for use in formulating the drug product for testing in clinical trials of Ropidoxuridine and RT of cancers.

The agreement with TCG GreenChem allows the Company to advance its clinical research, including its proposed Phase II clinical trials, to establish the data necessary for the FDA to determine efficacy in treating brain tumors, sarcomas and pancreatic cancers, diseases that offer potential for orphan designations. In conjunction with manufacturing Ropidoxuridine, TCG GreenChem will perform process research, development and optimization work for Shuttle Pharma related to Ropidoxuridine and create working standards of starting materials and intermediates to support the qualitative/quantitative analysis of the drug reaction progress, determination of impurities, total mass balance and assay yields of the reactions. Shuttle Pharma will own all intellectual property and improvements developed through the Manufacturing Agreement.

TCG GreenChem, Inc. was founded by former large pharma pharmaceutical executives with a track record in the development of hundreds of New Chemical Entities into the clinic and commercialization of several well-known pharmaceutical products for Boehringer Ingelheim Pharmaceuticals, Inc., Sepracor, Inc., and Merck & Co, Inc.

Engagement of Theradex Oncology

In November 2022, Shuttle announced it had engaged Theradex Oncology, a leading clinical research organization ("CRO"), to help prepare for its upcoming clinical study of Ropidoxuridine. Specifically, 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. 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.

Theradex Oncology has provided full oncology clinical trial services in the U.S. 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.

Patent Awards

In September 2022, Shuttle Pharma announced it had been awarded patents in the U.S. and Hong Kong for its radiation sensitizing HDAC inhibitor technology platform, which is focused on reducing side effects and improving outcomes for cancer patients treated with radiation therapy (RT). Histone deacetylase (HDAC) inhibitors have been described as "a novel class of drugs that target enzymes involved in regulation of critical cellular functions that can inhibit cancer growth and activate cellular immunity," according to Scott Grindrod, PhD, lead

inventor and Laboratory Director at Shuttle Pharmaceuticals.

Treatment with HDAC inhibitors allows regulation of gene expression by blocking HDAC enzyme activity and allowing genes to be “turned on” to express proteins involved in regulation of the cell cycle, DNA damage response and immune activation. Inhibiting HDAC enzymes can turn on tumor suppressor genes to help control cell division and slow down cancer progression. Non-cytotoxic, highly selective inhibitors target the histone deacetylase 6 (HDAC6) enzyme to stimulate the immune system for applications in the treatment of cancers, neurological diseases and immunological disorders.

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 IPO prospectus filed with the SEC on August 31, 2022, and any risk factors set forth in the Company’s Quarterly Report on Form 10-Q filed with the SEC on November 14, 2022, or any 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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