HedgePath Pharmaceuticals Granted Meeting with FDA to Discuss SUBA BCCNS Trial Data and Regulatory Pathway

HPPI preparing patient dossiers for a July face-to-face meeting with FDA with the goal of filing an NDA later in 2018 Additional promising clinical trial data also announced

FOR IMMEDIATE RELEASE -- TAMPA, FLORIDA (June 5, 2018) – HedgePath

Pharmaceuticals, Inc. (OTCQB:HPPI), a clinical stage biopharmaceutical company that discovers, develops and plans to commercialize innovative therapeutics for patients with cancer, announced that the U.S. Food and Drug Administration (FDA), has granted HPPI a face-to-face meeting to discuss the results obtained in HPPI's open label, Phase 2(b) clinical trial testing SUBA™Itraconazole in patients with Basal Cell Carcinoma Nevus Syndrome (BCCNS), also known as Gorlin Syndrome. BCCNS is a genetic cancer condition that causes multiple and often disfiguring skin lesions.

HPPI believes that this meeting (known as a Type C Meeting, which is scheduled to occur in July 2018), will provide the opportunity for HPPI to advocate for and gain further guidance from FDA relating to the anticipated filing by HPPI of a New Drug Application (NDA) for SUBA BCCNS later in 2018.

At the meeting with FDA, HPPI plans to perform a review of its BCCNS patient data to explain to FDA the clinical benefit of therapy on individual target lesions. HPPI believes that FDA is particularly interested in those lesions deemed "high risk" lesions by the guidelines established by the National Comprehensive Cancer Network as well as the effects of SUBA-Itraconazole therapy on overall tumor burden. High risk lesions are those of a size and/or location at risk of reoccurrence leading to surgical disfigurement and/or morbidity. HPPI is preparing these data on 38 patients who participated in its Phase 2(b) trial, 34 of whom have one or more high risk lesions, along with all target lesion measurements, whole body photography at baseline, as well as anatomic photography and photos of individual target lesions at each visit.

Nicholas J. Virca, HPPI's President and Chief Executive Officer, stated that "We are very much looking forward to sitting down with FDA to discuss our promising data with a view towards preparing and submitting an NDA for SUBA-BCCNS later this year. The briefing package we are preparing for FDA is based on the database lock for our trial that completed in late January 2018 for 38 patients, with 10 patients still on active dosing at that time."

"In terms of the latest study results," continued Mr. Virca, "we can report that eighteen (53%) patients in the trial with one or more serious target lesions achieved a greater than 30% reduction in target lesion burden with minimal side-effects and 41% experienced disappearance of one or more of these high risk lesions during the study period. SUBA-Itraconazole continues in general to be well tolerated, with the majority of adverse events (or AEs) and treatment-related AEs being low grade. Higher grade hepatic enzyme AEs (two grade 2 and two grade 3) occurred in only 4 of 38 patients, and in all cases, returned to normal range following a dose reduction of SUBAItraconazole which allowed those patients to continue on study."

As an open label study, HPPI has been able to follow and report the progress of this trial, and the impact of therapy on target BCC lesions. As of the last trial summary report at the end of April, 2018, HPPI was still dosing 9 patients who continue on therapy. These patients have a median time on study of 101 weeks and an average target tumor burden reduction of 51% compared to baseline, demonstrating the potential for SUBA-Itraconazole to be used as a chronic therapy for

BCCNS.

Readers are cautioned that no assurances can be given that the clinical study referenced herein will be found by FDA to be sufficient for an NDA filing or, if filed, that the NDA will be approved by FDA.

About SUBA-Itraconazole

HPPI's lead drug candidate, SUBA-Itraconazole, is a patent-protected formulation of itraconazole, an approved oral antifungal drug that has been in use for over 25 years. HPPI is the exclusive U.S. licensee (through Mayne Pharma, the majority stockholder of HPPI) of SUBA-Itraconazole for the treatment of cancer. Prior to research at Johns Hopkins University, itraconazole was not known to have any target in mammalian cells. Investigators at

Johns Hopkins discovered that itraconazole inhibits the hedgehog pathway by binding to a surface receptor in the pathway called Smoothened. Unlike generic itraconazole, that has poor and unpredictable bioavailability, SUBA-Itraconazole can be dosed at half the level of the generic formulation due to its superior bioavailability, which exceeds 90%. As such, HPPI believes that generic itraconazole cannot be substituted for SUBAItraconazole.

About BCCNS

HPPI's initial indication is for the orphan disease BCCNS. SUBA-Itraconazole has qualified under the FDA's Orphan Drug Designation Program as a potential therapy for BCCNS.

There is no approved pharmaceutical therapy for this familial cancer syndrome. There are estimated to be 10,000 patients in the U.S. with BCCNS. This is an autosomal dominantly inherited defect in the hedgehog pathway that causes the pathway to be up-regulated, resulting in hundreds or even thousands of basal cell carcinomas developing over the lifetime of the affected patients. In many types of cancers, the hedgehog pathway is basically hijacked by the cancer cells to assist their growth and metastatic spread, but in the case of basal cell carcinomas, whether in this hereditary syndrome or in the much more common, sporadic basal cell carcinomas, the hedgehog pathway has a mutation that makes it the sole driver of the development of BCC tumors. Inhibition of the pathway, then, can inhibit the appearance of new tumors, shrink existing tumors, and even cause some tumors to disappear altogether.

Cautionary Note Regarding Forward Looking Statements

This press release and any statements of representatives and partners of HedgePath Pharmaceuticals, Inc. (the "Company") related thereto contain, or may contain, among other things, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the actual timing for, or actual results of, the Company's clinical trial described herein, the Company's meeting with FDA or the FDA's review of any trial data or New Drug Application submitted by the Company to FDA as described herein) may differ significantly from those set forth or implied in the forward-looking statements (and may further differ from the interim study results described herein). These forward-looking statements involve numerous risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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https://investors.inhibitortx.com/2018-06-05-hedgepath-pharmaceuticals-granted-meeting-with-fda-to-discuss-suba-bccns-trial-data-and-regulatory-pathway