HedgePath Pharmaceuticals Announces Further Positive Interim Data in its Phase II(b) Cancer Trial

18 subjects with Basal Cell Carcinoma Nevus Syndrome who had 231 surgically eligible tumors complete 16 weeks of dosing with SUBA™-Itraconazole
Second interim analysis shows a statistically significant mean target tumor burden reduction (P<0.0001) and 11 of 18 trial subjects to date achieveing a 30% or greater reduction in target tumor burden

FOR IMMEDIATE RELEASE -- TAMPA, FLORIDA (October 20, 2016) – HedgePath

Pharmaceuticals, Inc. (OTCQB:HPPI), a clinical stage biopharmaceutical company that discovers, develops and plans to commercialize innovative therapeutics for patients with cancer, announced further positive interim data from its ongoing, open-label Phase II(b) clinical trial studying the effect of SUBA-Itraconazole (SUBA-Cap) oral capsules in patients with Basal Cell Carcinoma Nevus Syndrome (BCCNS), also known as Gorlin Syndrome. Initial positive interim data were first reported by HPPI in early August 2016.

BCCNS patients have a rare genetic mutation which can lead to the growth of as many as hundreds of primary basal cell carcinomas on the skin, even in non-sun exposed areas, throughout their lifetimes. The standard of care for BCCNS is surgical excision of selected basal cell carcinomas when the tumors reach a size that, based on location, is considered a threat to a vital structure, such as the eyelid, or a challange to complete excision with a good cosmetic outcome. Surgery does not affect the underlying pathology so, throughout their lifetime, these patients have existing basal cell carcinomas that grow larger, as well as new basal cell carcinomas that continue to appear and grow, making management of these cancers a life-long challenge in BCCNS.

In its present study to date, HPPI has treated 30 subjects with BCCNS. Twenty-three subjects are on active SUBA-Cap dosing and 7 subjects are off study (for a total of 30 subjects). Five of these subjects have completed at least 16 weeks of treatment. Each of the subjects enrolled in the trial exhibited significant basal cell carcinoma (BCC) target tumors at baseline, consisting of a minimum of 10 surgically eligible lesions, with a history of surgical removal of at least 10 BCC tumors. The data below are derived from a follow-on interim analysis of results in 18 subjects who have completed 16 or more weeks of SUBA-Cap dosing where no subject has demonstrated an increase in target tumor burden. The Objective Response Rate (ORR) is 61.1% based on 11 of the 18 subjects exhibiting a 30% or greater reduction in target tumor burden, with a mean target tumor burden reduction of 61.2% for the 11 responding subjects.

An independent biostatistical analysis was conducted based upon the specific completion point of 16 weeks dosing for those same 18 subjects. It revealed that the mean percent reduction in target tumor burden was 36.1% across all subjects when 7 subjects with SD (stable disease) and 11 subjects with PR (partial response) were included in the analysis. This equates to a Wilcoxin signed rank P-value of <0.0001.

Now that HPPI has collected additional subject data over a longer period of SUBA-Cap dosing, it is important to not only document those target lesions that respond to treatment, but to ascertain how long they continue to respond. Therefore, in the present interim analysis, HPPI also analyzed the “best response” and “duration of response” (DoR) data for 231 target lesions across the 18 subjects.

The DoR was an encouraging 27.2 weeks for the significant number of tumors responding to SUBACap treatment with 16 or more weeks of dosing. However, since the trial is not yet complete, DoR data continue to be collected for existing tumors that continue to respond and for additional tumors that demonstrate initial responses (defined as equal to or greater than 30% reduction in size) over time, which is then confirmed at an additional 4 weeks during the subject’s next visit to the clinical trial site. To date, 141 target lesions (61% of those studied) have responded to therapy with either a partial or complete response. 229 target lesions (99% of those studied) have not progressed (meaning they have not grown more than 20% in size) with only one target lesion requiring surgical excision.

*Excludes 2 of 231 tumors which grew more than 20%

The independent analysis of the target lesions (plotted above) reported that 71 tumors (or 31% of the target lesions studied) demonstrated a complete response (CR) and an additional 70 tumors (or 30% of the target lesions studied) demonstrated a 30% or greater reduction (PR). As mentioned above, the combined CR + PR

average was 61% based upon a range of 57.0% to 69.4% with a 95% confidence level.

HPPI intends to continue collecting data on subjects being enrolled and treated at 5 centers in the U.S. while it interacts with FDA regarding ongoing results demonstrating efficacy and tolerability for SUBA-Cap treatment for BCC in BCCNS patients where there continues to be an unmet need since no drug therapy is currently approved. HPPI believes that the current Phase II(b) trial may lead to a possible New Drug Application (NDA) filing with the FDA. While these latest statistical analyses appear to be predictive of the desired final study results, readers are cautioned that no assurances can be given that the final study results will match the interim results or that the study when completed will achieve its primary endpoint or that the study will be found by FDA to be sufficient for the filing of an NDA.

HPPI is very pleased with the positive progress in this trial to date and looks forward to continuing the trial with the hopes of aiding this patient population. HPPI is releasing this second round of interim data at this time because the trial has reached an important inflection point in terms of number of patients studied who have achieved at least a 30% reduction in target tumor burden. However, HPPI is not committing to providing further interim updates prior to the reporting of the final study results unless it determines that an update is warranted.

About BCCNS

BCCNS results from a genetic mutation which causes the Hedgehog pathway (a major regulator of processes in cells) to function improperly, leading to the chronic formation of basal cell tumors, including potentially disfiguring lesions on the face. Industry sources estimate that there are approximately 10,000 patients in the United States with BCCNS, which has qualified SUBAItraconazole under the FDA’s Orphan Drug Designation Program.

About SUBA-Itraconazole

SUBA-Itraconazole is a patented and proprietary itraconazole formulation that enhances the absorption of itraconazole to improve the bioavailability of orally administered drugs that are poorly soluble. The U.S. rights to SUBA-Itraconazole for the treatment of cancer are exclusively licensed to HPPI by an affiliate of Mayne Pharma Group Limited. SUBA-Itraconazole was developed to improve absorption and significantly reduce variability compared to generic itraconazole. These benefits provide enhancements to patients and prescribers with reduced intra- and inter-patient variability, enabling a more predictable clinical response and a reduction in the active drug quantity to deliver the required therapeutic blood levels.

About HedgePath Pharmaceuticals

HedgePath Pharmaceuticals, Inc. (OTCQB:HPPI) is a clinical stage biopharmaceutical company that is seeking to repurpose the FDA approved antifungal pharmaceutical itraconazole as a potential treatment for cancer. HPPI is the exclusive U.S. licensee of a patented formulation of itraconazole, called SUBA-Itraconazole, which clinical studies have shown to have greater bioavailability than generic itraconazole.

The Hedgehog signaling pathway is a major regulator of cellular processes in vertebrates, including cell differentiation, tissue polarity and cell proliferation. Based on published research, HPPI believes that inhibiting the Hedgehog pathway could delay or possibly prevent the development of certain cancers in humans. Leveraging research undertaken by key investigators in the field, HPPI plans to explore the effectiveness of SUBA-Itraconazole as an anti-cancer agent and to pursue its potential commercialization. HPPI is headquartered in Tampa, Florida. For more information, please visit www.hedgepathpharma.com.

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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 "forwardlooking 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

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