Inhibitor Investor Room

HedgePath Pharmaceuticals Launches Clinical Trial for its Proposed Cancer Treatment

Enrollment commenced in HPPI's Phase II(b) study of SUBATM-Itraconazole for treatment of basal cell carcinoma in patients with basal cell carcinoma nevus syndrome
Interim results anticipated by Q1 2016

FOR IMMEDIATE RELEASE - TAMPA, FLORIDA and SAN DIEGO, CALIFORNIA – August 21, 2015 – HedgePath Pharmaceuticals, Inc. (OTCQB:HPPI), a clinical stage biopharmaceutical company that discovers, develops and plans to commercialize innovative therapeutics for patients with cancer, announced today enrollment has commenced in its Phase II(b) SCORING (SUBA-Cap Objective Response in Gorlin's) clinical trial. HPPI will study the efficacy and safety of twice-daily dosing of SUBA-Itraconazole Oral Capsules as a potential therapy for basal cell carcinoma (BCC) in patients with basal cell carcinoma nevus syndrome (BCCNS), also known as Gorlin's Syndrome.

Nicholas J. Virca, HPPI's President and Chief Executive Officer, commented, "We are extremely pleased and enthused to launch our first clinical trial as a single arm, Phase II(b), multi-center, open-label, non-placebo-controlled study for which we plan to recruit up to 40 patients across three clinical trial sites in the US. Based on our enrollment objectives and the first phase of our study plan, we expect to be able to assess interim results in over half of these patients during the first quarter next year."

Based on an Investigational New Drug Application previously cleared by the Food and Drug Administration, the primary endpoint of HPPI's study is the objective response rate of BCC lesions to SUBA-Itraconazole in subjects with BCCNS, under which a meaningful response will be defined as a 30% or greater reduction in the cumulative size of target tumors, with an appropriate sample size to be 33 of the 40 patients in order to maintain a 90% power. A detailed description of the trial design and patient eligibility criteria can be found at ClinicalTrials.gov under the study identifier NCT02354261.

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 could potentially qualify SUBA-Itraconazole under the FDA's Orphan Drug Designation Program for treatment of BCC in this patient population.

"We believe BCCNS provides us with an ideal first opportunity to test SUBA-Itraconazole's anti-cancer potential," continued Mr. Virca. "There is a relatively well-defined molecular mechanism associated with BCCNS that causes patients to suffer from multiple, chronically recurring tumors which can be debilitating and often require disfiguring surgeries to remove cancerous lesions. Existing topical therapies have proven suboptimal due to lack of efficacy, and marketed oral therapies for BCC are only approved for locally advanced or metastatic basal cell carcinomas that are not candidates for radiation or surgery and carry significant side-effects that limit their chronic use. In our trial, the initial dosing period is 16 weeks to study the primary endpoint of tumor response rate, followed by an additional 24 weeks to collect ongoing efficacy and safety data. We anticipate this timeline will enable us to continue our interactions with FDA regarding assessment of clinically meaningful responses in BCCNS patients. We believe that our trial design lays out a well-defined regulatory pathway, and we are now moving forward to develop what we believe will be an effective treatment for this underserved patient population."

HPPI anticipates that if there is evidence of substantial clinical benefit to these patients, the company would seek to have further discussions with FDA as to whether results from this trial could potentially serve as the basis for a New Drug Application submission to FDA for this product candidate.

About HedgePath Pharmaceuticals

HedgePath Pharmaceuticals, Inc. 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 has offices in Tampa, Florida and San Diego, California. For more information, please visit www.hedgepathpharma.com.

About SUBA-Itraconazole

SUBA-Itraconazole is a proprietary itraconazole formulation that enhances the absorption of itraconazole to improve the bioavailability of orally administered drugs that are poorly soluble. SUBA-Itraconazole was developed to improve absorption and significantly reduce variability compared to generic itraconazole. These benefits enable a more predictable clinical response and a reduction in the active drug quantity to deliver the required therapeutic blood levels. SUBA is a trade mark of Mayne Pharma International Pty Ltd., which has exclusively licensed SUBAItraconazole to HPPI for use in the field of cancer in the United States.

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 or the FDA’s review of such results) may differ significantly from those set forth or implied in the forward-looking statements. 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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