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

13 Subjects with Basal Cell Carcinoma Nevus Syndrome
Who Had 167 Surgically Eligible Target Tumors Complete 16 Weeks Dosing

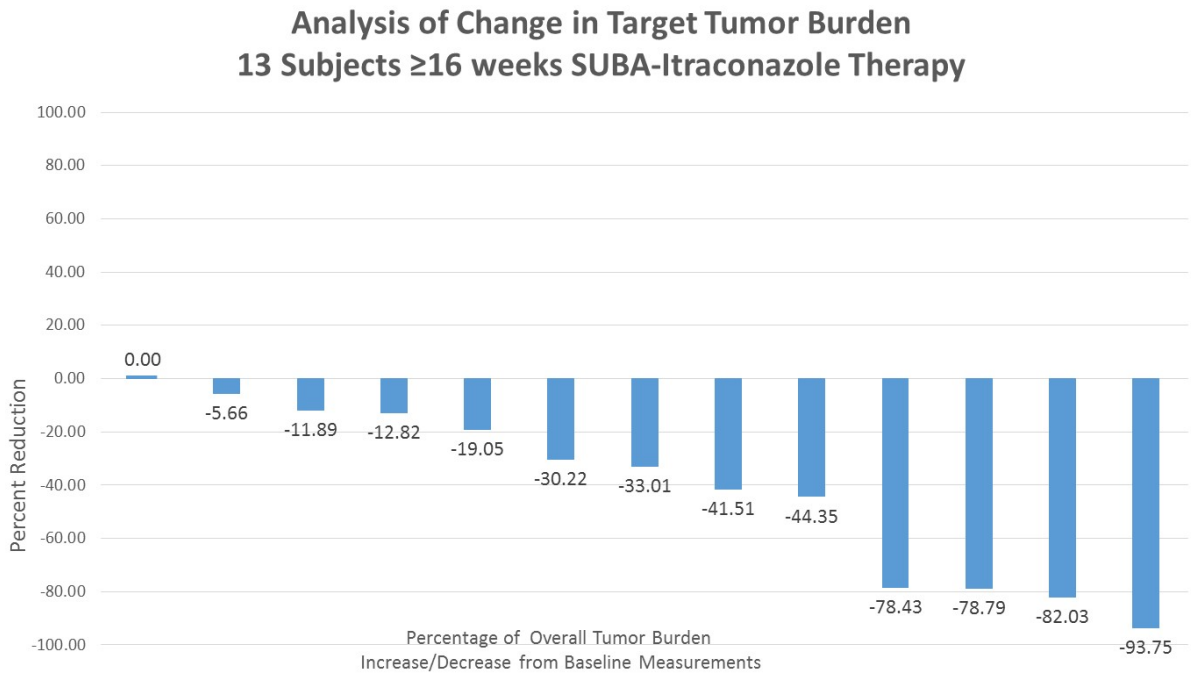
FOR IMMEDIATE RELEASE -- TAMPA, FLORIDA (August 3, 2016) – HedgePath Pharmaceuticals, Inc. (OTCQB:HPPI), a clinical stage biopharmaceutical company that discovers, develops and plans to commercialize innovative therapeutics for patients with cancer, announced positive interim data from its ongoing, open-label Phase II(b) clinical trial studying the effect of SUBA™-Itraconazole oral capsules in patients with Basal Cell Carcinoma Nevus Syndrome (BCCNS), also known as Gorlin Syndrome.

Patients with BCCNS develop multiple basal cell carcinomas (BCC) throughout their lifetime. The standard of care for these primary tumors is surgical removal, considered to be in the best interest of the patient to prevent further morbidity. These surgeries often lead to disfigurement with significant concern over primary tumors on the face. HPPI believes that an oral treatment for BCCNS could significantly improve the lives of effected patients.

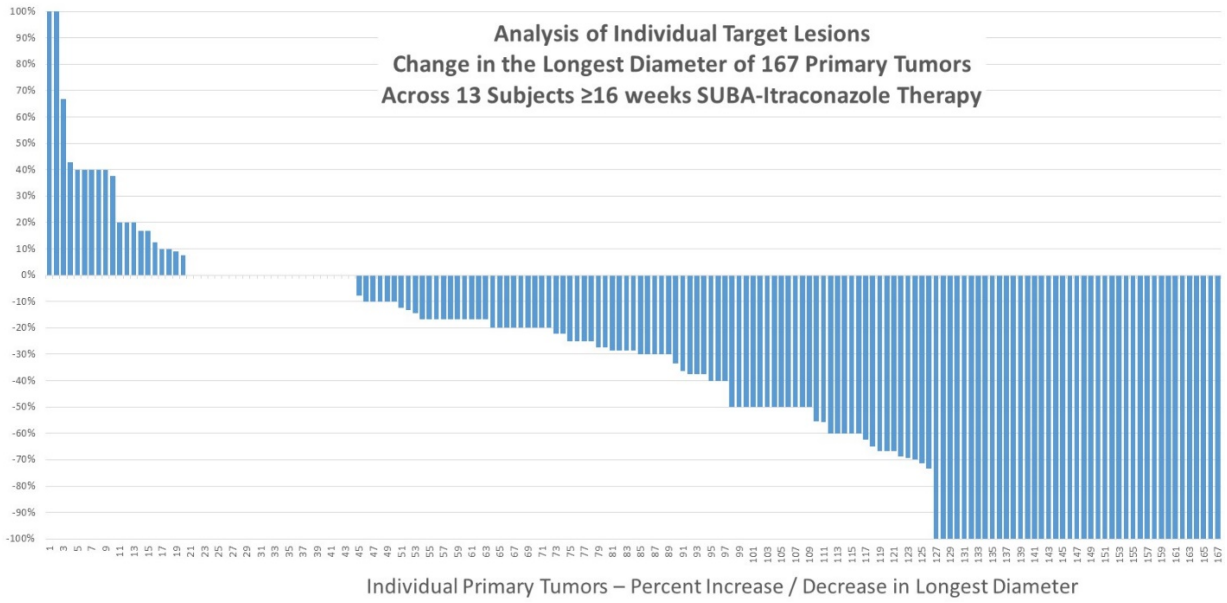
The data reported today are derived from HPPI's interim analysis of results in 13 subjects who have completed 16 weeks of SUBA-Itraconazole dosing. Each of these subjects was enrolled in the trial with a requirement that they exhibited significant basal cell carcinoma (BCC) target tumors at baseline consisting of a minimum of 10 surgically eligible lesions, and that they had a history of surgical removal of at least 10 BCC tumors. For each subject, 10 to 15 of the largest lesions are selected by the investigator at baseline to represent a valid sample of overall lesions.

HPPI has conducted two separate interim analyses: (i) the change in target tumor burden for each subject (which is based on the sum of the longest diameters for each subject's target lesions) to measure the change in target tumor burden from baseline; and (ii) the change in the longest diameter of all target lesions for all subjects in the study, which the company believes documents clinical impact, since the disappearance or reduction in size of individual tumors can delay or eliminate the need for surgical procedures that can lead to disfigurement.

With respect to target tumor burden, among those subjects who have now been dosed for at least 16 weeks, the target tumor burden has not increased in any subject and has been reduced by greater than 30% in 8 of the 13 subjects (62%) with an average reduction of 60%. In addition, HPPI's dosing regimen continues to be well tolerated with Grade 1 or no toxicity reported in 90% of subjects assessed to date in the trial, including an additional 6 subjects (total of 19) with 8 or more weeks of dosing.



With respect to changes in the longest diameter of individual target lesions, HPPI has conducted an interim analysis of 167 individual target lesions across all 13 subjects. Growth of a primary tumor increases the likelihood that an individual tumor will require surgical treatment. The interim analyses showed that 25% of these cancerous lesions have disappeared, an additional 25% have exhibited greater than a 30% reduction, and 42% have remained stable (< 20% increase and < 30% reduction). The overall average tumor reduction among responders has been a promising 75%. Although 8% of target lesions analyzed in the interim data have increased by more than 20% in longest diameter, to date no primary tumors have required surgical intervention.



Based on these encouraging interim results, 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-Itraconazole treatment for BCC in BCCNS patients where there continues to be an unmet need since no drug therapy is currently approved. HPPI does not anticipate additional reporting of interim results. If the final study results are consistent with the interim results, HPPI believes that the current Phase II(b) trial may lead to a possible New Drug Application filing with the FDA, but there can be no assurances given at this time that this will actually occur. While these interim results may not be predictive of the final study results, HPPI is very pleased with the positive progress to date and looks forward to continuing the trial with the hopes of aiding this patient population.

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 SUBA-Itraconazole 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.

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 (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.

For more information:

Nicholas J. Virca, President and CEO
nvirca@hedgepathpharma.com

Investor Relations Contact:
Garry Hasara, CFO & Treasurer
ghasara@hedgepathpharma.com

OR

Tim Ryan
The Shoreham Group
tryan@shorehamgroupllc.com