

FDA Grants Orphan Drug Designation to SUBA™-Itraconazole for Treatment of Patients with BCCNS

FOR IMMEDIATE RELEASE -- TAMPA, FLORIDA and SAN DIEGO, CALIFORNIA – (June 2, 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 today that it has received notice of Orphan Drug Designation for treatment of patients with Basal Cell Carcinoma Nevus Syndrome (BCCNS) with its oral formulation of SUBA-Itraconazole Capsules.

The FDA, through its Office of Orphan Products Development (OOPD), grants orphan status to drugs and biologic products that are intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S. Orphan drug designation provides a drug developer with certain benefits and incentives, including a period of marketing exclusivity if regulatory approval is ultimately received for the designated indication.

“We believe BCCNS provides us with an ideal first opportunity to test SUBA-Itraconazole’s anti-cancer potential,” said Nicholas J. Virca, President & CEO of HedgePath Pharmaceuticals. “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. We believe that our Phase II (b) trial design lays out a well-defined regulatory pathway, as we continue to move forward developing what we believe will be an effective treatment for this underserved patient population.”

HPPI anticipates that, based upon evidence of substantial clinical benefit in subjects currently enrolled in our clinical trial, the company will 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.

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 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 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 has offices in Tampa, Florida and San Diego, California. 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. 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

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