

## **HedgePath Pharmaceuticals Files IND Application**

**Company plans to commence clinical development of SUBA®-Itraconazole for treatment of basal cell carcinoma in patients with basal cell carcinoma nevus syndrome**

**FOR IMMEDIATE RELEASE - TAMPA, FLORIDA and SAN DIEGO, CALIFORNIA - November 18, 2014** -

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 filed an Investigational New Drug (IND) Application with the U.S. Food and Drug Administration (FDA) on Friday, November 14, 2014.

The IND covers HPPI's proposed clinical development of a patented formulation of the currently marketed anti-fungal drug itraconazole (known as SUBA-Itraconazole) for the treatment of basal cell carcinoma (BCC) in patients with basal cell carcinoma nevus syndrome (BCCNS).

The filing follows a pre-IND meeting held with FDA at which HPPI reviewed potential Phase II(b) trial considerations in order to gain FDA input on its clinical development strategy and protocol which HPPI now believes is reflected in its IND filing. If the IND is approved, HPPI would expect to commence patient recruiting to begin its clinical trial in the first quarter of 2015.

Nicholas J. Virca, HPPI's President and Chief Executive Officer, commented that, "This is a milestone moment for HPPI as we submit our first IND under which we will seek to repurpose our licensed, patented formulation of the FDA approved anti-fungal drug itraconazole as a candidate for anti-cancer therapy in humans. Based on existing third party data, we believe that itraconazole has the potential to inhibit the Hedgehog (Hh) Pathway, a major regulator of many fundamental cellular processes, which could in turn impact the development and growth of certain cancers. We believe this could serve as a treatment for skin, lung and prostate cancers, and we will begin to develop this approach with human testing for BCC tumor response in patients with BCCNS."

"We believe BCCNS provides us with an ideal first opportunity to test itraconazole's anti-cancer potential" continued Mr. Virca. "This is a relatively well-defined patient population that suffers from multiple 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 the only approved oral therapy for BCC has a significant side-effect profile. As such, we look forward to continuing our interactions with FDA, as we work to see this IND approved to study the safety and efficacy of SUBA-Itraconazole in these patients."

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. Nearly all individuals with BCCNS carry a mutation in the PTCH1 gene that results in constitutive activation of the Hh pathway. Itraconazole has been shown to inhibit the Hh pathway which plays an important role in basal cell carcinomas. Basal cell carcinoma is a skin cancer that commonly develops on sun exposed areas of fair-skinned individuals. BCC is generally a slow-growing tumor that does not metastasize (rate of metastasis estimated at no higher than 0.5%); however, it is locally invasive and can result in severe morbidity, especially in those patients with BCCNS who can develop hundreds or thousands of BCCs requiring frequent surgical intervention.

### **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](http://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 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.

## **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 results of the FDA's review of the Company's IND as described herein and any implied timing for or results of the Company's clinical trials) may differ significantly from those set forth in the forward-looking statements. These forwardlooking statements involve certain 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:**

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