

**HedgePath Pharmaceuticals Announces Positive FDA Feedback from FDA Type-C Meeting and Files Pre-NDA Meeting Request**  
**FDA has confirmed HPPI's clinical and regulatory pathway for SUBA BCCNS and provided further guidance for anticipated NDA submission**

**FOR IMMEDIATE RELEASE -- TAMPA, FLORIDA  
(August 6, 2018) - HedgePath**

Pharmaceuticals, Inc. (OTCQB:HPPI), a clinical stage biopharmaceutical company that discovers, develops and plans to commercialize innovative therapeutics for patients with cancer, announced that the U.S. Food and Drug Administration (FDA) has confirmed HPPI's current clinical and regulatory pathway related to HPPI's SUBA™ - Itraconazole as a treatment for Basal Cell Carcinoma (BCC) in patients with Basal Cell Carcinoma Nevus Syndrome (BCCNS, also known as Gorlin Syndrome). FDA's positive feedback was received at HPPI's previously announced July 23rd Type-C Meeting with FDA and was confirmed in minutes of the meeting received by HPPI from FDA.

Based on this feedback, HPPI as has filed a Pre-NDA Meeting Request with FDA as a next step toward the anticipated filing of HPPI's New Drug Application (NDA) for SUBA BCCNS during 2018.

Nicholas J. Virca, HPPI's President & CEO, stated "Based upon the positive exchange with FDA attendees during our Type-C Meeting and the publication of meeting minutes by the FDA only a few days later, we believe we have reached a better understanding with FDA regarding the reporting of our efficacy and safety results from our Phase 2(b) open label trial for SUBA BCCNS. We are also encouraged by the FDA's guidance concerning the other requirements for our anticipated NDA submission under the 505(b)(2) pathway. Based on these developments, we have submitted a PreNDA Meeting Request seeking an additional confirmatory meeting with FDA before the planned filing of our NDA for SUBA BCCNS later this year."

Readers are cautioned that no assurances can be given that the clinical study referenced herein will be found by FDA to be sufficient for an NDA filing or, even if the NDA is accepted for filing, that the NDA will be ultimately be approved by FDA.

## **About SUBA-Itraconazole**

HPPI's lead drug candidate, SUBA-Itraconazole, is a patent-protected formulation of itraconazole, an approved oral antifungal drug that has been in use for over 25 years. HPPI is the exclusive U.S. licensee (through Mayne Pharma, the majority stockholder of HPPI) of SUBA-Itraconazole for the treatment of cancer. Prior to research at Johns Hopkins University, itraconazole was not known to have any target in mammalian cells. Investigators at Johns Hopkins discovered that itraconazole inhibits the hedgehog pathway by binding to a surface receptor in the pathway called Smoothened. Unlike generic itraconazole, that has poor and unpredictable bioavailability, SUBA-Itraconazole can be dosed at half the level of the generic formulation due to its superior bioavailability, which exceeds 90%. As such, HPPI believes that generic itraconazole cannot be substituted for SUBA-Itraconazole.

## **About BCCNS**

HPPI's initial indication is for the orphan disease BCCNS. SUBA-Itraconazole has qualified under the FDA's Orphan Drug Designation Program as a potential therapy for BCCNS. There is no approved pharmaceutical therapy for this familial cancer syndrome. There are estimated to be 10,000 patients in the U.S. with BCCNS. This is an autosomal dominantly inherited defect in the hedgehog pathway that causes the pathway to be up-regulated, resulting in hundreds or even thousands of basal cell carcinomas developing over the lifetime of the affected patients. In many types of cancers, the hedgehog pathway is basically hijacked by the cancer cells to assist their growth and metastatic spread, but in the case of basal cell carcinomas, whether in this hereditary syndrome or in the much more common, sporadic basal cell carcinomas, the hedgehog pathway has a mutation that makes it the sole driver of the development of BCC tumors. Inhibition of the pathway, then, can inhibit the appearance of new tumors, shrink existing tumors, and even cause some tumors to disappear altogether.

# 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, the Company's meeting with FDA or the FDA's review of any trial data or New Drug Application submitted by the Company to FDA as described herein) 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.

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