# HedgePath Pharmaceuticals Secures Interim Financing To Commence Clinical Trials and Finalizes Key Agreement with Mayne Pharma

\$1.5 million in proceeds to fund 2014 commencement of HPPI's clinical development program for repurposing the approved anti-fungal drug itraconazole for the treatment of cancer, initially for the treatment of Basal Cell Carcinoma Nevus Syndrome

Mayne Pharma has acquired a significant minority stake in HPPI and, per previous agreement, will serve as HPPI's itraconazole manufacturer and supplier

FOR IMMEDIATE RELEASE -- TAMPA, FLORIDA and SAN DIEGO, CALIFORNIA – (June 25, 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 is has closed a \$1.5 million interim private common stock financing. The funds were secured from Hedgepath, LLC, HPPI's current majority stockholder. Under the terms of the financing, Hedgepath, LLC will purchase 20 million shares of HPPI common stock for gross proceeds of \$1.5 million, which proceeds will be funded in preagreed to monthly tranches during the remainder of 2014.

Concurrently with this funding, HPPI has finalized its previously announced Supply and License Agreement with Mayne Pharma Ventures Pty Ltd (Mayne Pharma), a wholly owned subsidiary of Mayne Pharma Group Limited, an Australian Stock Exchange listed company. Under related agreements entered into by HPPI and Mayne Pharma to finalize the Supply and License Agreement, Mayne Pharma has acquired shares of HPPI preferred stock and warrants to acquire HPPI common stock amounting to an approximately 40% fully diluted equity interest in HPPI.

HPPI is using the proceeds of the financing to support its filing of an Investigational New Drug (IND) Application aimed at securing FDA approval to begin a corporate-sponsored clinical trial with HPPI's primary drug candidate, SUBA™-Itraconazole for the treatment of basal cell carcinoma (BCC), and to commence and conduct such trial. HPPI holds the exclusive U.S. rights to SUBA-Itraconazole from Mayne Pharma for the treatment of cancer. Mayne Pharma will also supply SUBA-Itraconazole for HPPI's currently contemplated and future clinical trials.

HPPI intends to study the anti-cancer efficacy of SUBA-Itraconazole as a Hedgehog pathway inhibitor in a Phase II(b) trial as a treatment for BCC with a focus on seeking eventual regulatory approvals and marketing in the United States. SUBA-Itraconazole capsules will be tested as a stand-alone, daily oral therapy for treatment of BCC, with an initial emphasis on patients with BCCNS (basal cell carcinoma nevus syndrome, also known as Gorlin-Goltz Syndrome), for which HPPI intends to file for orphan drug designation. This initial effort in BCC is then expected to be expanded during 2015 to include non-BCCNS patients with poorly operable basal cell tumors to determine if, as may be the case for treatment of patients with BCCNS, a treatment that is less toxic than the currently approved Hedgehog inhibitor will be better suited as a chronic therapy for recurring tumors.

Earlier this month, HPPI began formal interaction with FDA and clinical investigators regarding an IND for BCCNS. Assuming FDA concurrence with its plans, HPPI intends to commence this first clinical trial in BCC during October 2014.

Nicholas J. Virca, HPPI's president and chief executive officer, stated that, "This is a milestone moment for our company. Our binding agreement with Mayne Pharma and our interim financing enables us to initiate our clinical programs designed around the re-purposing of itraconazole, which is an FDA approved anti-fungal drug, for new therapies in the treatment of cancer. We believe the patent-protected formulation of SUBA-Itraconazole will enhance clinical performance through improved drug delivery, at nearly twice the bioavailability of generic formulations of itraconazole, and enable low toxicity, chronic dosing that will achieve predictable therapeutic blood levels better suited for oncology applications, such as the daily dosing of patients with BCCNS who face the ongoing development of tumors throughout their lifetime. We are very excited to move forward with our IND and to begin our clinical trial work."

Also as part of these transactions, Hedgepath, LLC has agreed to forgive or exchange approximately \$640,000 of advances previously made to HPPI in consideration of the issuance to Hedgepath, LLC of shares of HPPI preferred stock and common stock and warrants to purchase common stock. Following this transaction, and assuming full funding of its \$1.5 million investment, Hedgepath, LLC owns an approximately 46.5% fully diluted interest in HPPI.

Additional details regarding the terms of the financing and the Mayne Pharma agreements will be made available in a Current Report on Form 8-K to be filed by HPPI with the Securities and Exchange Commission.

## **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. Itraconazole has also been shown to exhibit antiangiogenic properties (inhibiting the formation of new blood vessels in tumors) which can also impact the progression of certain cancers. Leveraging research undertaken by key investigators in the field, HPPI plans to explore the effectiveness of SUBA-Itraconazole as a cancer inhibitor and to pursue its potential commercialization. HPPI has offices in Tampa, Florida and San Diego, California. For more information, please visit <a href="https://www.hedgepathpharma.com">www.hedgepathpharma.com</a>.

### **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 timing for and results of the Company's anticipated 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:

#### **Company Contact:**

HedgePath Pharmaceuticals, Inc., Nicholas J. Virca, President and CEO, 813-864-2559, <a href="mailto:nvirca@hedgepathpharma.com">nvirca@hedgepathpharma.com</a>.

## **Investor Relations:**

HedgePath Pharmaceuticals, Inc., Garrison Hasara, CFO and Treasurer, 813-864-2560, <a href="mailto:ghasara@hedgepathpharma.com">ghasara@hedgepathpharma.com</a>

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