

## **HedgePath Pharmaceuticals Announces Expanded Patent Coverage**

**HPPI's patent portfolio expands with claims covering treatment of both hematologic and nonhematologic cancers with itraconazole, the active ingredient in HPPI's current and anticipated future product candidates**

FOR IMMEDIATE RELEASE -- TAMPA, FLORIDA (May 14, 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 today that the U.S. Patent and Trademark Office (USPTO) has issued a new patent to HPPI which expands the company's patent portfolio.

The new patent (No. 9,962,381, issued on May 8, 2018) is entitled "Treatment and Prognostic Monitoring of Cancerous Proliferation Disorders Using Hedgehog Pathway Inhibitors." The claims covered by the patent relate to the use of the already FDA-approved anti-fungal drug itraconazole being repurposed by HPPI to treat cancer. A patented formulation of itraconazole is being studied by HPPI as a product candidate for the treatment of cancer.

Nicholas Virca, HPPI's President and Chief Executive Officer, stated "This new patent, which has 21 claims, relates to methods for treating cancer by orally administering a formulation of itraconazole that confers superior bioavailability compared to conventional formulations of itraconazole. The patent covers treatment of hematologic cancers, such as leukemia or lymphoma, as well as non-hematologic cancers including lung, ovarian, breast, brain and pancreatic cancers. The patent claims also cover treatment of prostate cancer, basal cell carcinoma, and other cancers, and monitoring subjects undergoing such treatments based on biomarkers and other criteria predictive of efficacy. Issuance of this patent strengthens and expands the scope of patent protection provided by our first patent, U.S. Patent No. 9,192,609, which issued on November 24, 2015."

The basic premise behind HPPI's proposed therapy is that in certain cancers, the Hedgehog pathway, a major regulator of many fundamental cellular processes, malfunctions, thus leading to the formation of cancerous cells. Itraconazole appears to act on the essential Hedgehog pathway component called Smoothened (SMO) in a manner that is different than the FDA-approved drug vismodegib by preventing the ciliary accumulation of SMO normally caused by Hedgehog stimulation. Itraconazole also has a much shorter half-life than vismodegib, which may be the reason it has less side effects than vismodegib.

The new patent's claims also cover techniques for prognosticating an outcome of prostate cancer treatment with the itraconazole therapy, and for determining the efficacy of the therapy, based on post-therapy prostate-specific antigen levels. Unlike the majority of prostate cancer drugs, which target androgens in order to lower testosterone levels, the effect of itraconazole for treatment of prostate cancer is androgen-independent.

This expanded IP coverage supports HPPI's efforts in exploiting the many potential opportunities regarding Hedgehog pathway modulation as a "molecular indication" as opposed to narrower, cancer specific approvals.

### 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 is exploring 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](http://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 benefits of the new patent 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.

For more information:

Nicholas J. Virca, President and CEO

[nvirca@hedgepathpharma.com](mailto:nvirca@hedgepathpharma.com)

Investor Relations Contact:

Garrison Hasara, CFO and Treasurer

[ghasara@hedgepathpharma.com](mailto:ghasara@hedgepathpharma.com)

© 2018 HedgePath Pharmaceuticals, Inc. All rights reserved.

---

<https://investors.inhibitortx.com/2018-05-14-HedgePath-Pharmaceuticals-Announces-Expanded-Patent-Coverage>