Inhibitor Investor Room

HedgePath Pharmaceuticals Announces Notice of Allowability of U.S. Patent Application Regarding Treatment of Prostate Cancer

Twenty new claims for use of itraconazole as a means of Hedgehog pathway inhibition Patent expected to issue coincident with HedgePath's 2019 efforts to clear IND for SUBA®-Itraconazole for the treatment of prostate cancer

TAMPA, FL, MAY 6, 2019 – HedgePath Pharmaceuticals, Inc. (OTCQB:HPPI), a pharmaceutical development company focused on discovering, developing and ultimately commercializing innovative therapeutics to inhibit the progression of cancerous and noncancerous proliferation disorders, announced today that the U.S. Patent and Trademark Office (USPTO) has notified HedgePath that new claims have been allowed regarding the use of the anti-fungal drug itraconazole, and specifically the patented formulation of SUBAItraconazole in patients with prostate cancer. SUBA-Itraconazole is HedgePath's proprietary formulation of itraconazole and is designed to enable improved bioavailability compared to conventional itraconazole. HedgePath is the exclusive U.S. licensee of SUBA-Itraconazole in certain fields.

In the coming months, HedgePath intends to submit an IND (Investigational New Drug application) to the U.S. Food and Drug Administration (FDA) to study SUBA-Itraconazole treatment in patients with late-stage, advanced prostate cancer, and thereafter initiate a clinical trial once the IND is cleared.

This new patent, for which 20 claims have been allowed, relates to methods for treating both non-metastatic prostate cancer and metastatic castrate-resistant prostate cancer (mCRPC) by orally administering SUBA-Itraconazole. The claims also include the use of itraconazole in combination with chemotherapy regimens, which are the standard of care for late-stage prostate cancer patients. Additionally, the newly allowed claims cover techniques for prognosticating an outcome of prostate cancer treatment with itraconazole therapy and for determining the efficacy of the therapy, based on post-therapy prostate-specific antigen (PSA) levels.

Nicholas J. Virca, HedgePath's President and Chief Executive Officer, stated, "Our clinical development program for prostate cancer will test SUBA-Itraconazole in conjunction with standard of care chemotherapy to assess whether the combination regimen could be of clinical benefit for the approximately 23,000 men in the United States each year who are diagnosed with late-stage prostate cancer. These patients appear to become resistant to androgen deprivation therapy (ADT) due to up-regulation of the Hedgehog (Hh) pathway, a major regulator of many fundamental cellular processes. The issuance of this new patent for treatment of prostate cancer with SUBA-Itraconazole, and our planned IND submission in the coming months, represent meaningful progress toward the human testing of our proposed therapy for these patients."

In late-stage prostate cancer, up-regulation of the Hedgehog pathway may result in oncogene expression which interferes with the binding of ADT drugs to the androgen receptor (AR), thus causing biochemical resistance leading to mCRPC. Based on human testing, as well as *in vitro* studies, itraconazole appears to bind to the essential Hedgehog signaling pathway component in human cells 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. Based on pre-IND discussions with FDA to date, HedgePath believes that following IND clearance, the company will look to initiate a multi-center Phase 2b clinical trial seeking to demonstrate that the addition of SUBAItraconazole to standard of care chemotherapy can improve rPFS (radiographic progression free survival) in late-stage mCRPC patients.

About HedgePath Pharmaceuticals

HedgePath Pharmaceuticals, Inc. (OTCQB:HPPI) is a pharmaceutical development company that discovers, develops and plans to commercialize innovative therapeutics to inhibit the progression of cancerous and non-cancerous proliferation disorders. HedgePath is the exclusive U.S. licensee of SUBA-Itraconazole in certain fields. Clinical studies have shown SUBA-Itraconazole to have greater bioavailability than generic itraconazole, a drug that has been approved by FDA for the treatment of certain fungal infections. 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, HedgePath believes that inhibiting the Hedgehog pathway could delay or possibly prevent the development and progression of certain cancers, such as prostate cancer, in humans. Leveraging research undertaken by key investigators in the field, HedgePath is exploring the effectiveness of SUBA-Itraconazole as an anti-cancer agent and to pursue its potential commercialization. HedgePath is headquartered in Tampa, Florida. 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 anticipated benefits of the new patent and the timing for the submission and potential clearance of the IND and potential commencement of human trials 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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