Inhibitor Investor Room

HedgePath Pharmaceuticals Announces Notice of Allowance with Additional Claims Governing the Use of SUBA®-Itraconazole for the Treatment of Lung Cancer

New method of use claims in lung cancer enhance HedgePath's intellectual property estate relating to SUBA-Itraconazole

TAMPA, FL, MAY 29, 2019 – HedgePath Pharmaceuticals, Inc. (OTCQB:HPPI), a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapeutics to inhibit the progression of cancerous and non-cancerous proliferation disorders, announced today that it has received a notice of allowance from the U.S. Patent and Trademark Office with additional claims governing the use of the anti-fungal drug itraconazole, and specifically HedgePath's licensed, patented formulation of SUBA-Itraconazole, in patients with lung cancer. SUBA-Itraconazole is a 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, including lung cancer.

This new patent, for which 26 claims have been allowed, relates to treating lung cancer and, in particular, non-squamous, non-small-cell lung cancer (NSCLC) by orally administering SUBAItraconazole. The claims cover a broad range of factors including the use, delivery and techniques to determine and manage the response of SUBA-Itraconazole dosed in combination with second-line chemotherapy to reduce disease progression in treated patients. These new patent claims add to HedgePath's growing intellectual property (IP) estate for SUBA-Itraconazole and follow the company's recent announcement of method of use claims in the treatment of prostate cancer.

"We are pleased to receive additional claims for SUBA-Itraconazole in treating patients with lung cancer," commented Nicholas J. Virca, President and Chief Executive Officer of HedgePath. "These patent claims represent further validation of the technology's potential in treating latestage cancers where therapeutic options may be limited for many patients. With this additional IP in place, we will be better positioned to protect and capitalize on our future investments in SUBA-Itraconazole for NSCLC."

According to the American Cancer Society, lung cancer is the leading cause of cancer-related deaths in the U.S., responsible for approximately 160,000 deaths a year—more than colon, breast and prostate cancer combined. Patients with advanced NSCLC have many options when considering therapies to extend survival. However, as reported in numerous scientific presentations over the last few years at ASCO (the American Society of Clinical Oncology), only half of patients with advanced NSCLC are candidates for targeted chemotherapy with tyrosine kinase inhibitor drugs or the newer immunotherapies, thus creating a need for alternative therapies to be used in combination with existing treatments.

A randomized physician-sponsored Phase 2 study showed itraconazole given in combination with chemotherapy significantly improved median overall survival in patients with non-squamous NSCLC from eight months to 32 months, compared to chemotherapy alone. HedgePath is planning a clinical program to evaluate SUBA-Itraconazole dosing in combination with secondline chemotherapy therapy to delay disease progression in this same patient population. HedgePath plans to initiate discussions with the U.S. FDA (Food and Drug Administration) during 2020 regarding a Phase 2b clinical program to study SUBA-Itraconazole in patients with latestage lung cancer.

About SUBA-Itraconazole

SUBA-Itraconazole (which stands for "super bioavailability") is a patented formulation of itraconazole designed to improve the bioavailability of orally administered drugs that are poorly soluble. SUBA-Itraconazole has improved absorption and significantly reduced variability compared to generic Itraconazole, providing patients and prescribers with reduced intra- and inter-patient variability, enabling a more predictable clinical dose response and a reduction in the active drug quantity required to deliver therapeutic levels into the bloodstream. SUBAItraconazole is manufactured by Mayne Pharma under current Good Manufacturing Practice standards for

HedgePath’s use in clinical trials. An affiliate of Mayne Pharma is HedgePath’s majority stockholder and the licensor of the SUBA-Itraconazole technology.

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 SUBAItraconazole 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 SUBAItraconazole 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 proposed submission of an IND 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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