Inhibitor Investor Room

HedgePath Pharmaceuticals Provides Corporate Update for the Fourth Quarter and Year End 2018

Corporate Highlights:

- Secured the potential for up to $5 million in new funding ($1.5 million of which has been funded to date) and further secured a 9% royalty on future U.S. sales of SUBA®Itraconazole for basal cell carcinoma nevus syndrome (BCCNS) through revised agreement with majority shareholder and licensor Mayne Pharma Ventures Pty Ltd. (Mayne Pharma)

- Secured exclusive option to license next-generation itraconazole analogues from University of Connecticut (UCONN) for potential pipeline expansion, and exploring additional assets to acquire or license

- Significantly expanded intellectual property for oral itraconazole covering the treatment of a broad range of cancers and non-cancerous proliferation disorders

- Actively seeking pre-IND meeting for SUBA-Itraconazole for Prostate Cancer during first half of 2019, with the goal of initiating human trials in 2019, and also exploring other product candidates for acquisition or license

Tampa, FL, March 7, 2019 – HedgePath Pharmaceuticals, Inc. (OTCQB: HPPI), a pharmaceutical development company focused on discovering, developing and ultimately commercializing innovative therapies for patients with certain cancers and non-cancerous proliferation disorders, today provided a business update for the fourth quarter and year ended December 31, 2018.

HedgePath is focused on advancing its oral itraconazole-based drug candidate, SUBAItraconazole, for the treatment of advanced prostate and lung cancers in anticipated upcoming clinical studies. In 2018, HedgePath successfully completed Phase 2(b) trial studying the effects of SUBA-Itraconazole in patients with BCCNS. In addition, a body of clinical evidence further supports the potential use of oral itraconazole to treat patients with unmet needs in other types of cancer.

“We believe our considerable efforts throughout 2018 position HedgePath positively for the future as we seek to augment the potential value of SUBA-Itraconazole,” stated Nicholas J. Virca, President and Chief Executive Officer of HedgePath. “The results of our Phase 2(b) trial of SUBAItraconazole for the treatment of BCCNS were positive, and we are hoping to replicate similar results with future clinical trials utilizing

SUBA-Itraconazole."

"As previously announced, in September 2018, the FDA unexpectedly required additional efficacy and safety data and analyses to support our new drug application (NDA) for SUBAItraconazole for BCCNS. As a result of this guidance, and due to pending contractual deadlines under our existing supply and license agreement with our majority stockholder Mayne Pharma, we agreed with Mayne Pharma to revise our agreement such that Mayne Pharma assumed responsibility for the further development of SUBA-Itraconazole for BCCNS at its cost in exchange for various economic and other considerations that enable HedgePath to focus on advancing SUBA-Itraconazole in a focused field of additional indications where oral itraconazole has shown clinical efficacy. We believe the opportunities we're now pursuing with SUBAItraconazole in advanced prostate and lung cancer represent a pathway toward accelerated development and potential approval, which should translate to enhanced value for patients with unmet needs as well as for our shareholders."

"We expect to hold a pre-IND meeting with the FDA in the second quarter of 2019 and, subject to FDA clearance, our plan is to initiate a Phase 2(b) clinical study for SUBA-Itraconazole in men with metastatic, castration-resistant prostate cancer before the year's end," said Mr. Virca. "In addition, we plan to advance SUBA-Itraconazole into a clinical program for patients with advanced non-squamous non-small cell lung cancer in 2020. Physician-led Phase 2 studies of oral itraconazole in these patient populations demonstrated significant efficacy signals, including progression-free survival and overall survival, giving us confidence that our SUBA-Itraconazole formulation may have a meaningful impact when dosed in addition to standard of care chemotherapy. As in BCCNS, we expect to benefit from the FDA's accelerated 505(b)(2) regulatory pathway for our prostate and lung cancer programs, as well as other potential incentive programs such as Breakthrough Therapy Designation or FDA Fast Track if our clinical data support it. Importantly, under our revised agreement with Mayne Pharma, our development programs for SUBA-Itraconazole in prostate and lung cancer and other licensed indications do not have early termination provisions for not achieving specific development targets as was previously the case for the SUBA-Itraconazole BCCNS Program."

Mr. Virca concluded, "We believe HedgePath is poised to achieve important milestones in 2019 and beyond as we continue to advance our clinical pipeline along its trajectory. The expansion of our intellectual property portfolio in 2018 to cover oral itraconazole for the treatment of a range of different cancers and cell proliferative diseases enables us to maximize the value of our core platform, and in parallel, we are exploring ways to expand our product candidate portfolio and add value to our company by evaluating additional assets to acquire or license. For example, we're currently conducting pre-clinical studies using next-generation itraconazole analogues through our exclusive option agreement with UCONN and will continue to evaluate additional assets opportunistically with a focus on innovative therapeutics that address unmet needs and orphan indications. Finally, with the support of Mayne Pharma, one of our corporate finance goals is to uplist HedgePath's stock to a national stock exchange, which we believe would enhance our visibility among professional biotech investors and support our corporate initiatives."

Financial Highlights:

On December 17, 2018, HedgePath announced that it had entered into a revised Supply and License Agreement with Mayne Pharma. In consideration of the transfer to Mayne Pharma of the SUBA-Itraconazole BCCNS clinical data and regulatory rights, HedgePath will receive a 9% royalty on future net sales of SUBA-Itraconazole BCCNS in the U.S. (subject to FDA approval and deductions for HedgePath's continuing access to certain third party patents), as well as $3 million in non-dilutive funding, structured in stages as a discounted advance on the such future 9% royalties. In addition, HedgePath will have the right to receive, in its discretion, up to $2 million in added royalty advances should HedgePath secure $3 million in new funding from third parties by June 30, 2021. Also, Mayne Pharma agreed to amend the terms of its existing Series B Convertible Preferred Stock to remove a redemption right of Mayne Pharma related to such securities, allowing HedgePath to fully classify such preferred stock as equity on its balance sheet at December 31, 2018.

As of December 31, 2018, HedgePath had cash and cash equivalents of $1.1 million. Net loss for year ended December 31, 2018 was $4.6 million, or $0.01 per basic and diluted share, compared to a net loss of $5.1 million, or $0.01 per basic and diluted share, for the same period in 2017.

Additional details regarding HedgePath's results of operations, business and related risk factors can be found in the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which is being filed with the SEC today.

About HedgePath Pharmaceuticals, Inc.

HedgePath is a pharmaceutical development company focused on discovering, developing and ultimately commercializing innovative therapies for patients with certain cancers and noncancerous proliferation disorders. The Company's initial focus is to advance its oral itraconazolebased technology, SUBA-Itraconazole, for the treatment of prostate and lung cancers, utilizing the FDA's accelerated 505(b)(2) regulatory pathway. SUBA-Itraconazole is a patented oral formulation of the anti-fungal drug itraconazole that is designed for significantly improved oral bioavailability, enabling a lower effective dose and a more predictable clinical response. HedgePath's lead programs are clinically de-risked with proven bioavailability, safety and antitumor efficacy, and HedgePath intends to initiate a Phase 2(b) clinical study in patients with advanced castration-resistant prostate cancer by the end of 2019, subject to IND clearance by the FDA.

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 development activities 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 previously disclosed by the Company). 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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