HedgePath Pharmaceuticals and Mayne Pharma Enter into Updated Collaboration and Funding Agreements

HPPI to transfer SUBA-Itraconazole BCCNS clinical program to Mayne Pharma in consideration of up to $5 million in new funding from Mayne Pharma and a 9% royalty on future SUBA-Itraconazole BCCNS sales in the U.S. With new funding, HPPI to move towards IND filing during 2019 and recruitment to initiate human trials for SUBA-Itraconazole Prostate HPPI also to pursue expansion of product candidate pipeline with non-SUBA itraconazole analogue technology with University of Connecticut

FOR IMMEDIATE RELEASE -- TAMPA, FLORIDA (December 17, 2018) – HedgePath

Pharmaceuticals, Inc. (OTCQB:HPPI) announced today that it has entered into a revised Supply and License Agreement (SLA) with its majority stockholder Mayne Pharma Ventures Pty Ltd (Mayne Pharma), an affiliate of Mayne Pharma Group Limited (ASX: MYX).

Under the new SLA, Mayne Pharma will assume control of the regulatory and clinical development program for SUBA®-Itraconazole for the treatment of basal cell carcinoma nevus syndrome (SUBA-Itraconazole BCCNS) in anticipation of conducting a global Phase 3 pivotal clinical trial based on results achieved in the Phase 2(b) trial conducted by HPPI in the U.S. Mayne Pharma will immediately assume responsibility for all future SUBA-Itraconazole BCCNS-related expenses.

In consideration of the transfer to Mayne Pharma of the SUBA-Itraconazole BCCNS clinical data and regulatory rights, HPPI will receive the following consideration:

- a 9% royalty on future net sales of SUBA-Itraconazole BCCNS in the U.S. (subject to deductions for HPPI's continuing access to certain third party patents).

- $3 million of new funding in stages tied to the transfer of SUBA-Itraconazole BCCNS to Mayne Pharma. This funding, which is expected to be completed by mid-2019, will be non-dilutive since it is structured as a discounted advance on the future 9% royalties receivable by HPPI (although if SUBA-Itraconazole BCCNS is not approved in the U.S. by the end of 2023, Mayne Pharma may recapture such discounted advances in the form of common stock of HPPI at the then current market value of HPPI's common stock).

- In addition, if HPPI is able to secure $3 million in new funding from third parties by June 30, 2021, at HPPI's election, Mayne Pharma will make additional royalty advances of up to $2 million on the same terms. This commitment by Mayne Pharma of an additional $2 million in funding may alternatively be satisfied if Mayne Pharma elects to participate in future equity financings of HPPI.

- The SLA will continue in effect, and the exclusive field covered by the SLA has been focused to specifically comprise prostate, lung and certain other non-cancer proliferation disorders. Mayne Pharma will have the right to exploit SUBA-Itraconazole in all other

  fields in the U.S., including BCCNS. Importantly, HPPI's continued right to work on these indications will no longer be tied to the achievement of clinical or commercial target dates. HPPI is now working towards the submission of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for SUBA-Itraconazole for the treatment of prostate cancer (SUBA-Itraconazole Prostate), with the goal of having that IND cleared, allowing HPPI to proceed to recruitment for initiating human trials.

- In addition, Mayne Pharma will continue to provide quantities of SUBA-Itraconazole drug and placebo oral capsules for HPPI's SUBA-Itraconazole Prostate clinical study, with an agreed amount to be provided without charge.

- In addition, unlike under the previous SLA, Mayne Pharma has licensed to HPPI the right to use all pre-clinical or clinical trial or other data generated or owned by Mayne Pharma related to the current SUBA-Itraconazole formulation anywhere in the world for HPPI's activities in the U.S. in a specified field under the new SLA.

- In addition, Mayne Pharma has agreed that it will support a reverse stock split of HPPI's common stock should HPPI request this in connection with HPPI's exploration of an uplisting to a senior stock exchange and associated capital raise.

- Finally, Mayne Pharma has agreed to amend the terms of its existing Series B Convertible Preferred Stock to remove Mayne Pharma's future right to require HPPI to redeem such securities, which will allow HPPI to fully classify such preferred stock as equity on its balance sheet.

Additional details of the transaction will be available in a Current Report on Form 8-K to be filed by HPPI with the SEC.

This transaction arose out of a right of Mayne Pharma under the previous SLA to assume control of SUBA-Itraconazole BCCNS after December 31, 2018 for a 9% royalty on future net sales of SUBA-Itraconazole BCCNS in the U.S. if a New Drug Application (NDA) for SUBA-Itraconazole BCCNS was not accepted for filing by FDA by December 31, 2018. As previously announced, based on unforeseen requirements imposed by FDA in September 2018, HPPI determined that it would be unable to responsibly file the SUBA-Itraconazole BCCNS NDA by this deadline, and thus HPPI commenced negotiations with Mayne Pharma to transfer SUBA-Itraconazole BCCNS in advance of December 31, 2018 on negotiated terms beneficial to HPPI. During these negotiations, HPPI actively undertook activities aimed at filing the SUBA-Itraconazole BCCNS NDA within the timeframes required under the SLA, but ultimately concluded in its business judgment based on significant regulatory guidance that such a filing, even if it could be accomplished, would imperil the regulatory acceptance and viability of the SUBA-Itraconazole BCCNS asset to the detriment of HPPI's shareholders. HPPI believes that Mayne Pharma's indication that it plans to undertake a Phase 3 study of SUBA-Itraconazole BCCNS validates HPPI's strategic conclusions related to the present transaction with Mayne Pharma.

The transaction was negotiated and approved on behalf of HPPI by a special committee of disinterested, independent members of HPPI's Board of Directors.

Nicholas Virca, HPPI's President and Chief Executive Officer, stated that "It has taken a considerable effort to reach these important agreements with our majority stockholder, Mayne Pharma, and we thank them for working with us to achieve this outcome. We believe, taking into consideration all of the facts and circumstances, that enabling Mayne Pharma to pursue SUBA Itraconazole BCCNS on advantageous terms to HPPI gives us a fresh start as a research and development company, with $3 million of near term funding and the possibility of an additional $2 million, a less restrictive SLA with Mayne Pharma with no development targets or deadlines, and access to worldwide SUBA-Itraconazole data to support our future business plans."

"Moving forward, our 2019 focus is to seek a pre-IND meeting with FDA, with the goal of reaching agreement with FDA on the endpoints for initiating a clinical trial of SUBA-Itraconazole Prostate. We commissioned a market study which included interviews with key opinion leaders to help us target a potential therapy for over 27,000 men who have metastatic castrate resistant prostate cancer who are no longer responding to androgen deprivation therapy (also known as ADT). As with SUBA-Itraconazole BCCNS, we intend to follow the 505(b)(2) regulatory pathway to accelerate our clinical testing program for SUBA-Itraconazole Prostate. Our goal will be to have our IND for SUBA-Itraconazole Prostate cleared by FDA and to begin efforts in recruiting patients for the prostate clinical trial before the end of 2019" continued Mr. Virca.

"Beyond SUBA-Itraconazole, we are planning to work with other compounds for the treatment of cancer in an effort to expand our product candidate pipeline. As announced earlier this year, we hold a world-wide exclusive option from the University of Connecticut regarding its patented chemical analogues of itraconazole to treat cancerous and non-cancerous indications. These next generation formulations of itraconazole appear to have reduced off-target side effects while exhibiting improved pharmacokinetic properties and a reduced concern associated with the use of many other drugs that are contraindicated for patients receiving itraconazole. A preclinical testing program is now underway to assess the effectiveness of the lead compound in treating certain cancers via hedgehog pathway inhibition in a well-established mouse model. If the pre-clinical results prove to be encouraging, we would expect to exercise our option and to begin efforts to outsource manufacturing to produce cGMP product as part of a program to move into human testing in 2020" concluded

Mr. Virca.

Scott Richards, Mayne Pharma's Chief Executive Officer, stated "Mayne Pharma remains committed to supporting HPPI and its leadership to pursue the clinical development, registration and commercialization of SUBA-Itraconazole for the treatment of oncology indications in the U.S. The management of HPPI has successfully progressed SUBA-Itraconazole BCCNS through its first major clinical program. We believe out-licensing our SUBA-Itraconazole intellectual property in the U.S. in this focused field through the partnership with HPPI provides Mayne Pharma shareholders with a significant stake in potentially multiple novel cancer programs. We look forward to working with HPPI to further these development programs."

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.

For more information:

Nicholas J. Virca, President and CEO

nvirca@hedgepathpharma.com

Investor Relations Contact:

Garrison Hasara, CFO and Treasurer

ghasara@hedgepathpharma.com

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https://investors.inhibitortx.com/2018-12-17-hedgepath-pharmaceuticals-and-mayne-pharma-enter-into-updated-collaboration-and-funding-agreements