Inhibitor Investor Room

HedgePath Pharmaceuticals To Receive $2.5 Million in Funding From Mayne Pharma

HedgePath to shortly commence Phase II(b) skin cancer trial using Mayne Pharma's SUBATM-Itraconazole

FOR IMMEDIATE RELEASE -- TAMPA, FLORIDA and SAN DIEGO,

CALIFORNIA – (May 18, 2015) – 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 it has entered into a definitive agreement with an affiliate of Mayne Pharma Group Limited (ASX: MYX) under which Mayne Pharma will invest $2.5 million in HPPI in a private common stock and warrant financing. The closing of the financing is expected to occur within five business days.

HPPI will use this funding to immediately accelerate its development program, which is focused on the treatment of certain cancers using Mayne Pharma's patented oral formulation of the currently approval anti-fungal drug itraconazole, known as SUBA-Itraconazole, for which HPPI has exclusive U.S. rights in the field of cancer. In particular, HPPI will shortly be commencing a Phase II(b) clinical trial designed to determine the safety and effectiveness of SUBA-Itraconazole dosing on the reduction in individual patient tumor burden in patients with Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome). Preliminary results are expected to be available by early 2016.

Mayne Pharma's CEO, Mr. Scott Richards said "We are excited about increasing our stake in

HPPI and accelerating the development and commercialization of our patented SUBAItraconazole for the treatment of cancer. The body of evidence supporting the use of itraconazole in cancer is well established, and we believe our SUBA-Itraconazole product provides a number of advantages over conventional itraconazole, including improved bioavailability and more consistent blood levels to improve the therapeutic effect."

Nicholas J. Virca, HPPI's President and CEO, further commented that, "This investment by Mayne Pharma enables us to immediately begin efforts to open clinical trial sites during this quarter for our Phase II(b) study, following the protocols which were cleared by FDA in December 2014."

BCCNS results from a genetic mutation, which causes the Hedgehog pathway to function improperly leading to the chronic formation of basal cell tumors. Industry sources estimate that there are approximately 10,000 patients in the United States with BCCNS, which could potentially qualify for SUBA-Itraconazole under the FDA's Orphan Drug Designation Program for treatment of BCCNS in this patient population.

"Our Phase II(b) design is a single-arm, multi-center, open-label, non-placebo controlled study which will involve the recruiting of up to 40 patients where a meaningful response will be defined as a 30% or greater reduction in the cumulative size of target tumors, based upon the clinical evaluation of at least 33 of 40 patients. We plan to report preliminary results by early 2016, after assessing the effectiveness and safety of 16 weeks of dosing in these patients," commented Mr. Virca. He continued that, "If the results demonstrate we have achieved our primary endpoint, we will initiate further discussions with FDA to determine if our trial could potentially serve as the basis for accelerated approval and submission of a New Drug Application."

In the financing, for its $2.5 million investment, Mayne Pharma will receive 33,333,333 shares of HPPI common stock, bringing its position in HPPI to 49.5% of the currently outstanding common stock, and a 5-year warrant to purchase an additional 33,333,333 shares of HPPI common stock.

HPPI, Mayne Pharma and certain related parties have also entered into updated agreements covering HPPI and Mayne Pharma's joint development of SUBA-Itraconazole for the treatment of cancer as well as certain governance matters relating to HPPI given Mayne Pharma's increased ownership in the company.

Additional details regarding this transaction and all related documentation will be provided in a Current Report on Form 8-K to be filed by HPPI with the Securities and Exchange Commission.

About HedgePath Pharmaceuticals

HedgePath Pharmaceuticals, Inc. 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 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 plans to explore the effectiveness of SUBA-Itraconazole as a cancer inhibitor and to pursue its potential commercialization. HPPI has offices in Tampa, Florida and San Diego, California. For more information, please visit www.hedgepathpharma.com.

About SUBA-Itraconazole

SUBA-Itraconazole is a proprietary itraconazole formulation that enhances the absorption of itraconazole to improve the bioavailability of orally administered drugs that are poorly soluble. SUBA-Itraconazole was developed to improve absorption and significantly reduce variability compared to generic itraconazole. These benefits provide enhancements to patients and prescribers with reduced intra- and inter-patient variability, enabling a more predictable clinical response and a reduction in the active drug quantity to deliver the required therapeutic blood levels.

About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes globally; either directly or through distribution partners and also provides contract development and manufacturing services.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialized in numerous products that have been marketed around the world.

Mayne Pharma has two drug development and manufacturing facilities based in Salisbury, Australia and Greenville, North Carolina, with expertise in formulation complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.

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 outcome of the Company's collaboration with Mayne and timing for and results of the Company's anticipated clinical trials) may differ significantly from those set forth in the forward-looking statements. These forward-looking statements involve certain 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:

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