Immune Pharmaceuticals, Inc. Issues Letter to Shareholders

Englewood Cliffs, NJ, August 4, 2017 (BusinessWire) – Immune Pharmaceuticals Inc. (NASDAQ; IMNP) a clinical stage biopharmaceutical company specializing in the development of novel targeted therapeutic agents in the fields of immuno-inflammation, dermatology and immuno-oncology, issued the following Letter to Shareholders.

Dear Immune Shareholder,

Set out below are a review of our asset portfolio for our new shareholders who may be unfamiliar with our robust pipeline, a summary of our strategic business plan for unlocking our intrinsic value, the status of our ongoing clinical trials and associated upcoming milestones, certain financial highlights and a statement of our strategic objectives.

Background – Asset portfolio

Immune was established in 2011 with the license from iCo Therapeutics Inc. ("iCo") of bertilimumab for all human indications, other than ocular indications. iCo obtained bertilimumab from Cambridge Antibody Technology Group Plc (now part of AstraZeneca).

Bertilimumab is a first-in-class, humanized monoclonal antibody that targets and lowers eotaxin-1 levels in many inflammatory conditions. Eotaxin-1 is a low molecular weight molecule, known as a chemokine, which plays a role in immune responses and modulates the cross-talk between key cells involved in immuno-inflammation. Bertilimumab may prevent the migration of eosinophils and other cells by neutralizing eotaxin-1, thus helping to relieve associated inflammatory conditions. Currently, we are conducting two Phase 2 clinical trials to test bertilimumab in patients suffering from bullous pemphigoid and ulcerative colitis, respectively. We are planning to explore the clinical potential of bertilimumab in Severe Atopic Dermatitis, NASH and other orphan eosinophilic diseases, emphasizing our research in diseases with few or limited treatment options, including rare and orphan conditions.

We acquired EpiCept Corporation ("EpiCept") a specialty pharmaceutical company initially focused on the development and commercialization of topically-delivered prescription pain management therapeutics in 2013 and up-listed to NASDAQ in August 2014.

Among the assets that we acquired from EpiCept was Ceplene® (histamine dihydrochloride), a first-in-class, small molecule, targeting the Histamine-2 Receptor. Our oncology subsidiary, Cytovia Inc. ("Cytovia") intends to commercialize Ceplene for use in conjunction with low dose Interluken-2 ("IL-2") as a means to overcome immunosuppression in Acute Myloid Leukemia ("AML") and potentially other malignancies. Ceplene is designed to suppress tumor growth by inhibiting NOX-2, in turn inhibiting macrophage and leukemic cell ROS production, allowing IL-2 activation of Natural Killer ("NK") cells and T cytotoxic cells ("T cells") with consequent leukemic cell death. On June 15, 2017, we regained worldwide ownership of Ceplene through the acquisition of the rights in territories previously sold to Meda (now part of Mylan). Ceplene is approved in 30 European countries for remission maintenance post first complete remission in patients with. The addressable market for Ceplene in Europe is estimated to be 7,000 patients.

Recently, Cytovia entered into an exclusive licensing agreement with Pint Pharma International S.A. ("Pint"), a specialty pharmaceutical company focused on Latin America and other markets, for the marketing, commercialization and distribution of Ceplene throughout Latin America. Pint is planning to initiate registration activities for Ceplene in Latin America based on Ceplene's European approval and to implement an Early Access Program for patients with AML. Additionally, Pint intends to invest \$4 million in equity into Cytovia in conjunction with the spin off process.

Also among the assets that we acquired from EpiCept was AmiKet, a prescription topical analgesic cream. AmiKet contains a patented formulation, the contents of which include two FDA-

approved drugs, amitriptyline and ketamine. We are moving forward with a plan to sell or out-license this non-core asset.

In 2016, we acquired an exclusive license of a topical nano-capsule formulation of cyclosporine, which we refer to as NanoCyclo, from BioNanoSim Ltd., an Israeli company led by Professor Simon Benita, former Head of the Drug Research Institute at the Hebrew University of Jerusalem. This novel, stable formulation of cyclosporine is the first to leverage nanotechnology to ensure local dermal penetration of and minimize systemic exposure to cyclosporine, a drug used orally for the treatment of psoriasis and atopic dermatitis. We plan to initiate human proof of concept studies in those indications later this year.

Strategic business plan – Refocusing and restructuring

Our strategic business plan may be summarized as follows: we aim to unlock Immune's intrinsic value by focusing our human capital and financial resources on our bertilimumab and NanoCyclo product candidates while streamlining our operations by divesting our unrelated oncology business.

Recently, we announced our plan to pursue a spin-off of Cytovia into a separate, stand-alone company. Cytovia will focus on the development and commercialization of novel immuno-oncology and hematology therapeutics, including Ceplene, Azixa, crolibulin and the Company's bispecific antibody platform. Additionally, Cytovia may seek to acquire additional commercial stage drugs in the field of immuno-oncology. We expect Cytovia to develop this oncology platform more effectively and efficiently as a spun off company than as part of a larger business and thereby maximize this platform's value.

As part of the spin-off process, Cytovia will prepare a Form 10 registration statement for filing with the SEC. A Form 10 is used by private companies to register a class of securities with the SEC. An effective Form 10 registration statement allows, for example, for institutional public equity funds that have been restricted from investing in the private company to invest in such public, non-trading securities. In addition, as part of the spin-off process, we intend to distribute to our (Immune) shareholders as a dividend, shares in the spun-off Cytovia Inc., and Cytovia anticipates applying for listing of its securities on an eligible NASDAQ trading market at the appropriate time, which shall be subject to satisfaction of the NASDAQ exchange listing criteria and approval. Currently, Cytovia is forming a distinct management team under the leadership of Dr Daniel Teper as CEO and Cytovia's consulting CFO, who is joining Cytovia from a global pharmaceutical company.

Concurrently, we are strengthening Immune's management team. To this end, we have been interviewing and anticipate a near term announcement of the retention of a new chief medical officer who will bring the requisite experience and specialized expertise in medical affairs, drug development and biotechnology finance and operations.

Bertilimumab clinical trial status

We are actively recruiting patients in our bertilimumab phase 2 trials.

Bullous pemphigoid ("BP") is an orphan auto-immune skin blistering disease. IMNP BP-01, <u>An</u> <u>Open-Label, Proof of Concept Study Designed to Evaluate the Safety, Efficacy and Pharmacodynamic</u> <u>Effect of Bertilimumab in Newly Diagnosed Patients and Patients Resistant to Corticosteroid Tapering</u> <u>with Moderate to Extensive Bullous Pemphigoid</u> is an open-label, proof-of-concept, single group study in adult patients with newly diagnosed, moderate to extensive BP or taper resistant patients. The primary objective of this study is to evaluate the safety of bertilimumab and the secondary objective is to evaluate the preliminary evidence of clinical efficacy as measured by the BPDAI score (a severity outcome measure). We have enrolled patients at Mount Sinai Medical Center in New York City and at four sites in Israel and expect to complete the study later this year. Preliminary results indicate a reduction in patients' BPDAI by an average of 84%; a tapering down of oral prednisone to 10 mg or less; and no reports of significant adverse events. We look forward to the completion of this proof-of-concept study and subsequent publication early in 2018.

In April 2017, we filed an orphan drug application with the Office of Orphan Products Development of the FDA to obtain Orphan Drug Designation for bertilimumab in BP. Our efforts were supported by Pr. Neil Korman, Director, Clinical Trials Unit, UH Cleveland Medical Center; Director, Murdough Family Center for Psoriasis, UH Cleveland Medical Center; Professor, Dermatology, CWRU School of Medicine, and member of the Company's Scientific Advisory Board, who presented preliminary data with bertilimumab from the IMNP BP-01 study at the American Academy of Dermatology 2017 Annual Meeting in Orlando, Florida. Although there can be no assurance, we anticipate that we will obtain Orphan Drug designation for the pharmaceutical product within the next few months.

Ulcerative colitis ("UC") is a disease that causes inflammation and sores (ulcers) in the lining of the large intestine. It usually affects the lower section (sigmoid colon) and the rectum but it can affect the entire colon. IMNP UC-01, *Evaluation of Safety, Efficacy, Pharmacokinetic and Pharmacodynamic of Bertilimumab in Patients with Active Moderate to Severe Ulcerative Colitis* is a randomized, double blind, placebo-controlled, parallel group, multi-center study, seeking to enroll 42 adult patients with active moderate to severe UC. The primary objective of the study is to evaluate the safety and efficacy of bertilimumab, measured by a reduction in the Mayo Clinic Ulcerative Colitis Disease Index at 8 weeks, and the secondary objective is to evaluate mucosal injury and clinical remission. Patients are selected based on Mayo score and high levels of tissue eotaxin-1 as well as other standardized clinical criteria. We have enrolled patients at 5 sites in Israel and 1 site in Russia and expect to complete the study in the second quarter of 2018.

Financial highlights – Refinancing of secured debt

On July 7, 2017, we refinanced approximately \$3 million of outstanding senior secured debt owed to Hercules Capital, Inc. ("Hercules") by issuing a senior secured convertible promissory note with a principal amount of \$2,974,159. Whereas the original secured debt required significant monthly cash amortization payments, the replacement debt is repayable in shares or cash, at our option, allowing us to proactively manage our cash position. The replacement debt is repayable over a 12 month period and we may prepay the debt at any time (upon 10 days' notice) in cash at 115% of principal amount and accrued interest.

Other financial highlights completed recently include regaining NASDAQ compliance and reducing our monthly burn rate significantly.

<u>Conclusion – Strategic objectives</u>

Immune's mission is to develop innovative medicines that transform the lives of people living with severe inflammatory diseases. We intend to carry out this mission by demonstrating, through clinical trials, that the use of eotaxin-1 antibody therapeutics, such as bertilimumab, to reduce eotaxin-1 levels, is a viable treatment approach for select inflammatory diseases. Moreover, we intend to exemplify and promote the highest level of scientific integrity, shareholder accountability, and social responsibility in the conduct of our business. Immediate and necessary actions that we are undertaking to accomplish these goals include reorganizing the company to make it more efficient, including through the spin-off of our oncology business, dispensing with non-core programs and making personnel adjustments and cost effective decisions with respect to our office locations and laboratory. Our intention is to conserve cash and execute strategic transactions in an effort to increase near and longer term shareholder value.

I look forward to updating you on developments related to Immune's programs in the future and thank you for your support.

Sincerely,

Elliot Maza Interim Chief Executive Officer

Safe Harbor Statements Regarding Forward Looking Statements

This news release, and any oral statements made with respect to the information contained in this news release, may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal" or the negative of those words or other comparable words to be uncertain and forward-looking. Such forward-looking statements include statements that express plans, anticipation, intent, contingency, goals, targets, future development and are otherwise not statements of historical fact. Forward-looking statements include, among others, statements regarding the Company's ability to reduce expenses, capitalize on strategic alternatives, develop its assets, and generate value for shareholders. These statements are based on our current expectations and are subject to risks and uncertainties that could cause actual results or developments to be materially different from historical results or from any future results expressed or implied by such forward-looking statements.

There can be no assurance that the Company will ever successfully complete its anticipated corporate restructuring or spin-off, or that the Company will be able to reduce expenses, capitalize on strategic alternatives, develop its assets, and generate value for shareholders. Factors that may cause actual results or developments to differ materially include, but are not limited to: the risks associated with the adequacy of our existing cash resources and our ability to continue as a going concern; the risks associated with our ability to continue to meet our obligations under our existing debt agreements; the risk that ongoing or future clinical trials will not be successful; the risk that our compounds under development will not receive regulatory approval or achieve significant commercial success; the risk that we will not be able to find a partner to help conduct future trials or commercialize our product candidates on attractive terms, on a timely basis or at all; the risk that our product candidates that appear promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later-stage clinical trials; the risk that we will not obtain approval to market any of our product candidates; the risks associated with dependence upon key personnel; the risks associated with reliance on collaborative partners and others for further clinical trials, development, manufacturing and commercialization of our product candidates; the cost, delays and uncertainties associated with our scientific research, product development, clinical trials and regulatory approval process; our history of operating losses since our inception; the highly competitive nature of our business; risks associated with litigation; and risks associated with our ability to protect our intellectual property. These factors and other material risks are more fully discussed in our periodic reports, including our reports on Forms 8-K, 10-Q and 10-K and our other filings with the U.S. Securities and Exchange Commission.

You are urged to carefully review and consider the disclosures found in our filings, which are available at www.sec.gov or at www.immunepharma.com. You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be wrong due to inaccurate assumptions, unknown risks or uncertainties or other risk factors. We expressly disclaim any obligation to publicly update any forward-looking statements contained herein (including those relating to the corporate reorganization and exploration of strategic alternatives), whether as a result of new information, future events or otherwise, except as required by law.

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For further information, contact: investors@immunepharma.com