

## **Immune Pharmaceuticals Receives FDA Guidance for Low Dose IL-2 in Combination with Phase III Pivotal Trial of its AML Therapy Ceplene®**

New York, NY, October 27, 2016: Immune Pharmaceuticals (NASDAQ:IMNP) (Immune) announced today that it has received guidance from the United States Food and Drug Administration (FDA) on a phase III study for Ceplene in combination with low dose IL-2 for the maintenance of remission in patients with Acute Myeloid Leukemia (AML). Ceplene/IL-2 has previously been approved in Europe and Israel following a successful phase III study with Leukemia Free Survival as the primary endpoint. The proposed phase III study design reviewed by the FDA focuses on overall survival as the primary endpoint, along with key secondary endpoints, including Leukemia Free Survival.

The FDA also provided feedback relating to specific design elements of the phase III study, and with this framework, Immune plans to submit the final protocol for the phase III study in early 2017 and, upon approval, proceed with conducting a global Phase III Pivotal Overall Survival Study in AML maintenance of response with Ceplene/IL2.

“We are very pleased with the positive outcome of our recent interaction with the FDA. Our path forward to proceed with a pivotal study following regulatory guidance of Ceplene/IL-2 meets our goal to address the urgent unmet medical need for remission maintenance therapy in AML,” stated Monica Luchi, MD, Immune’s Chief Medical Officer.

### **About Immune Pharmaceuticals Inc.:**

Immune Pharmaceuticals Inc. (NASDAQ: IMNP) applies a personalized approach to treating and developing novel, highly targeted antibody therapeutics to improve the lives of patients with inflammatory diseases and cancer. Immune's lead product candidate, bertilimumab, is in Phase II clinical development for moderate-to-severe ulcerative colitis as well as for bullous pemphigoid, an orphan autoimmune dermatological condition. Other indications being considered for development include atopic dermatitis, Crohn's disease, severe asthma and Non-Alcoholic Steato-Hepatitis (NASH), an inflammatory liver disease. Immune recently expanded its portfolio in immuno-dermatology with topical nano-formulated cyclosporine-A for the treatment of psoriasis and atopic dermatitis. Immune's oncology pipeline includes Ceplene® which is in late stage clinical development for maintenance remission in Acute Myeloid Leukemia (AML) in combination with IL-2. Additional oncology pipeline includes Azixa® and crolibulin, Phase II clinical stage vascular disrupting agents, and novel technology platforms; bispecific antibodies and NanomAbs™. Maxim Pharmaceuticals Inc., Immune’s pain and neurology subsidiary is developing AmiKet™ and AmiKet™ Nano™ for the treatment of neuropathic pain. For more information, visit Immune's website at [www.immunepharma.com](http://www.immunepharma.com), the content of which is not a part of this press release.

### **Forward-Looking Statements**

This news release and any oral statements made with respect to the information contained in this news release 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. 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. Factors that may cause actual results or developments to differ materially include, but 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 clinical trials for bertilimumab, Ceplene, Azixa, AmiKet, AmiKet Nano, LidoPain or NanoCyclo will not be successful; the risk that bertilimumab, AmiKet or compounds arising from our NanomAbs program 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 the Phase III trials for AmiKet on attractive terms, on a timely basis or at all; the risk that our other product candidates that appeared 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; risks associated with the contemplated transaction with NPT. 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 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](http://www.sec.gov) or at [www.immunepharma.com](http://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, whether as a result of new information, future events or otherwise, except as required by law.

SOURCE: Immune Pharmaceuticals Inc.

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