

## **IMMUNE Pharmaceuticals' Oncology Subsidiary, CYTOVIA, Announces Additional Clinical Trial Results on the Efficacy of Ceplene® in Combination with Low-Dose IL-2 in Patients With Acute Myeloid Leukemia, Recently Published in *Leukemia*, a Leading Hematology Journal**

***Sixty-seven per cent of patients with functional natural killer (NK) cells remained disease-free at a pre-determined end point that followed two years of treatment***

NEW YORK, July 5, 2017 /PRNewswire/ -- Cytovia, the oncology subsidiary of Immune Pharmaceuticals Inc., a clinical stage biopharmaceutical company (NASDAQ: IMNP) ("Immune" or the "Company") announced the publication of clinical trial results on the use of Ceplene (histamine dihydrochloride) for relapse prevention in patients with acute myeloid leukemia (AML). The results were published in the leading hematology journal, *Leukemia*, published by Springer Nature. Investigators from the Universities of Gothenburg, Sweden and Rome, Italy reported that functional NK cells are clinically relevant anti-leukemic effector cells in AML patients who received treatment with Ceplene/IL-2.

Specifically, the investigators identified that approximately 60% of the AML patients who had received treatment with Ceplene/IL-2 harbored NK cells that were potentially reactive with the patient's leukemic cells. The "Re:Mission" phase IV trial results showed that 67% of patients with functional, autoreactive NK cells remained relapse-free for a pre-scheduled follow-up of 2 years vs. 11% relapse-free survival in corresponding patients devoid of active NK cells (p=0.0002, n=39). The results were based on analyses of the "Re:Mission" phase IV trial in AML, in which adult patients received Ceplene and low-dose IL-2 to prevent life-threatening relapses. For details of the trial design, please visit <https://clinicaltrials.gov/ct2/show/NCT01347996?term=ceplene&rank=1>.

The full text of the article published in *Leukemia* may be found at:  
<https://www.nature.com/leu/journal/vaop/naam/pdf/leu2017151a.pdf>.

"These results imply that potentially a large proportion of AML patients harbor efficacious anti-leukemic NK cells that are activated during immunotherapy with Ceplene in combination with low-dose IL-2. Additionally, NK cell profiling may contribute to optimally select patients who are suitable for treatment", said Fredrik Bergh Thorén, PhD, senior author of the *Leukemia* paper.

Cytovia's Dr. Daniel Teper added: "We are impressed by the quality of new scientific and clinical data, which further supports the relevance of Ceplene/IL-2 treatment for AML patients post first remission in preventing potentially life-threatening relapses of leukemia. Immune/Cytovia has been granted orphan drug designation for the use of Ceplene in combination with low-dose IL-2 in AML and is eligible for protocol assistance, potential R&D grants, waived FDA fees, tax credits and seven-year market drug exclusivity following approval in the United States."

Most patients with AML achieve complete remission from leukemia after receiving chemotherapy. However, the majority of adult patients experience relapse of AML, with poor prospects of long-term survival. Ceplene used in conjunction with low-dose Proleukin (interleukin-2) has been developed to prevent relapses in the post-chemotherapy phase of AML. A previous phase III trial in 320 patients confirmed the efficacy of Ceplene/IL-2 in preventing relapse of AML.

Ceplene in combination with low-dose IL-2 has been approved in more than 30 countries in Europe and in Israel for the treatment of AML and for maintenance of remission and prevention of relapse of leukemia. Currently, there are no approved therapies to prevent relapse for the vast majority of AML patients. An international Overall Survival study, REMAIN, is planned to support approval in the United States.

### **About Ceplene**

Ceplene (histamine dihydrochloride) is an immunostimulant that is administered in conjunction with low-dose interleukin-2 for maintenance of first remission in patients with AML. Ceplene has been shown in an international phase III clinical study to prevent relapse of leukemia in AML patients in first remission while maintaining good quality of life during treatment. Ceplene acts by countering dysfunction and apoptosis of T and NK cells, thereby inducing immune-mediated killing of leukemic cells, providing a strong pharmacological rationale for this combination therapy. A Phase IV study presented at the meeting of the American Association for Cancer Research in 2016 supported the safety and efficacy of Ceplene as demonstrated in the international phase III study. As previously announced, Immune, through its oncology subsidiary, Cytovia, entered into an Asset Purchase Agreement on June 15, 2017 with Meda Pharma SARL, a Mylan N.V. company, to repurchase the remaining worldwide rights to Ceplene which it did not own previously.

### **About AML**

AML patients receive intensive induction treatment with chemotherapeutic drugs at diagnosis and typically become free of detectable leukemia, achieving "complete remission". However, within 1-2 years the majority of adult patients will experience a relapse of leukemia, of which the prognosis for survival is 33% in patients' younger than 60 years of age and 15-20% in patients over 60 years of age. According to the American Cancer Society, there will be approximately 21,380 new cases of AML and 10,590 deaths from AML in the US in 2017. AML represents an orphan indication with a particularly high unmet medical need.

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

Immune Pharmaceuticals Inc. (NASDAQ: IMNP) is dedicated to alleviating the burden of patients suffering from autoimmune diseases by developing novel immunotherapeutic agents. Immune's lead product candidate, bertilimumab, is in Phase 2 clinical development for bullous pemphigoid, an orphan autoimmune dermatological condition, and for ulcerative colitis. Other potential relevant indications for bertilimumab include atopic dermatitis, Crohn's disease, severe asthma and Non-Alcoholic Steato-Hepatitis (NASH). Also, Immune's pipeline includes topical nano-formulated cyclosporine-A for the treatment of psoriasis and atopic dermatitis and AmiKet™ and AmiKet™ Nano™ for the treatment of neuropathic pain.

Immune's oncology subsidiary, Cytovia, plans to develop and commercialize Ceplene in combination with low-dose IL-2 for maintenance remission in AML. Additional oncology pipeline products include Azixa® and crolibulin, which are clinical stage vascular disrupting agents, and bispecific antibodies and NanomAbs™, which are novel technology platforms.

For more information, please 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, 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 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](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 (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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