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New Clinical Data Support Bertilimumab Activity in Bullous Pemphigoid

No anti-drug antibodies observed and multidose pharmacokinetics as expected

FORT LEE, N.J., Oct. 29, 2018 (GLOBE NEWSWIRE) -- [Immune Pharmaceuticals, Inc.](#) (OTCQB: IMNP) ("Immune" or the "Company"), a biopharmaceutical company developing novel therapeutic agents for the treatment of immunologic and inflammatory diseases, today released additional results from its positive, proof-of-concept phase 2a trial of bertilimumab in bullous pemphigoid. These results include pharmacokinetic (PK), pharmacodynamic (PD) and anti-drug antibody data.

The key observations are:

- No anti-drug antibodies were observed in any subject at any timepoint.
- The PK profile of bertilimumab in elderly bullous pemphigoid patients is similar to the profile observed in young, healthy volunteers and supports a once every other week dosing regimen.
- The mean serum concentration of autoantibodies to BP180 (type 17 collagen), which are important in the pathogenesis of BP, declined over the course of the study. In three subjects who experienced flares during the study, BP180 autoantibody levels increased during the flares.
- Serum eotaxin-1 levels rose during treatment, which may reflect binding of eotaxin-1 to bertilimumab, and then returned towards baseline after the third dose of bertilimumab.
- The mean serum concentration of eosinophil cationic protein (ECP), which is an enzyme released by eosinophils during degranulation, decreased over the course of the study. Six of the nine subjects had low baseline ECP levels that remained low throughout the study, whereas three subjects had elevated baseline levels that fell. The baseline ECP level did not correlate with disease severity or the clinical course.

"These results are consistent with the clinical observations previously reported for the BP-01 study," commented Immune's interim Chief Executive Officer, Tony Fiorino, MD, PhD. "The absence of anti-bertilimumab antibodies is a very positive safety finding, and we are happy that the multidose PK profile in elderly patients is similar to what was predicted based on the single-dose PK profile observed in healthy volunteers."

"The PD data are also quite encouraging," continued Dr. Fiorino. "BP180 levels are known

to be associated with disease severity, so the decline observed in the study correlates well with the clinical improvements that were observed. The transient elevation in serum eotaxin-1 levels during treatment, which occurred while subjects showed an impressive improvement in disease activity, was observed in prior bertilimumab studies, does not appear to have clinical significance and may reflect eotaxin-1 bound to bertilimumab. Finally, our observations regarding ECP as a potential biomarker in BP are consistent with the findings of the few prior studies addressing ECP in BP patients, and suggest that collecting a larger data set in the planned pivotal study will be worthwhile.”

Clinical results from the BP-01 phase 2a study (clinicaltrials.gov identifier [NCT02226146](https://clinicaltrials.gov/ct2/show/study/NCT02226146)) were previously presented in February 2018 at the American Academy of Dermatology Annual Meeting and in May 2018 at the Pre-IID Pemphigus and Pemphigoid Symposium. Subjects in the study experienced substantial improvements in disease activity despite receiving only three doses of bertilimumab and a low dose of prednisone that was rapidly tapered. The Company expects to continue the clinical development of bertilimumab with a planned pivotal phase 2/3 study when clinical supplies are available from the new manufacturing process, expected in late 2019 or early 2020.

About Immune Pharmaceuticals, Inc.

Immune Pharmaceuticals Inc. is a biopharmaceutical company developing novel therapeutic agents for the treatment of immunologic and inflammatory diseases. Immune's lead program, bertilimumab, is a first-in-class, human monoclonal antibody that targets eotaxin-1, a chemokine that plays a role in immune responses and attracts eosinophils to the site of inflammation. By blocking eotaxin-1, bertilimumab may prevent the migration and activation of eosinophils and other cells, thus blocking an important inflammatory pathway active in a variety of allergic and immune diseases. Bertilimumab has shown promising clinical activity in bullous pemphigoid and has been studied in other conditions including allergic rhinitis and ulcerative colitis, and may have application in other diseases, including atopic dermatitis, asthma, and other diseases. Immune is also developing NanoCyclo, a nano-encapsulated formulation of cyclosporin, which is in late stage preclinical development for atopic dermatitis and psoriasis. For more information, please visit www.immunepharma.com and connect with the Company on [Twitter](#), [LinkedIn](#), and [Facebook](#).

Safe Harbor Statements Regarding Forward Looking Statements

The statements in this news release made by representatives of Immune relating to matters that are not historical facts, including without limitation, those regarding future performance or financial results, the timing or potential outcomes of research collaborations or clinical trials, any market that might develop for any of Immune's product candidates and the sufficiency of Immune's cash and other capital resources, Immune's ability to fund its operations, the continued development by Immune of bertilimumab are forward-looking statements that involve risks and uncertainties, including, but not limited to, the likelihood that actual performance or results could materially differ, that future research will prove successful, the likelihood that any product in the research pipeline will receive regulatory approval in the U.S. or abroad, or Immune's ability to fund such efforts with or without partners. Immune undertakes no obligation to update any of these statements. In addition, there can be no assurance that Immune will be able to reduce expenses, capitalize on strategic alternatives, develop its assets, and generate value for

shareholders. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as to the date hereof. Accordingly, any forward-looking statements should be read in conjunction with the additional risks and uncertainties detailed in Immune's filings with the Securities and Exchange Commission, including those discussed in Immune's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and periodic reports filed on Form 8-K.

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