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ASIA EDITION

Dr. Reddy's announces positive results for psoriasis drug study

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PPC-06 is an extended release formulation of a fumaric acid ester (FAE), in-licensed from Xenoport, Inc. for further development to treat moderate to severe plaque psoriasis.

Dr. Reddy's has announced positive topline results from its Phase 2b study of PPC-06 (formerly referred to as XP23829) in patients with moderate to severe plaque psoriasis. In the study, PPC-06 met both co-primary endpoints i.e. PASI-75 and IGA scores of 0 or 1 with at least a 2-point reduction from baseline, after 24 weeks of oral treatment. The detailed safety and efficacy data from the study will be presented in future dermatology conferences.

"PPC-06 is an oral molecule with a novel mechanism of action that has the potential to address unmet medical needs of psoriasis patients. The topline data we are reporting today support our belief that PPC-06 may become the first approved oral prodrug of Monomethyl Fumarate (MMF) for treatment of moderate to severe plaque psoriasis in the U.S. Further clinical development requirements will be discussed with the US FDA to support the approval of this product," said Anil Namboodiripad PhD., Senior Vice President and Head, Proprietary Products Business.

PPC-06 is an extended release formulation of a fumaric acid ester (FAE), in-licensed from Xenoport, Inc. for further development to treat moderate to severe plaque psoriasis. A Phase 2b clinical study was conducted to evaluate the tolerability, safety and efficacy of three doses of PPC-06 over 24 weeks. This was a randomized, double-blind, placebo-controlled, dose-finding multicenter efficacy and safety study conducted at 76 sites in the U.S. Patients had stable, moderate to severe plaque psoriasis for at least 6 months, with PASI (Psoriasis Area and Severity Index) score ?12, IGA (5-point Investigator's Global Assessment) scores ?3, and psoriasis lesions involving 10% or more of the patient's Body Surface Area (BSA) at study baseline. A total of 426 patients were randomized in a 1:1:1:1 ratio into 4 treatment arms: 400 mg QD, 400 mg BID, 600 mg BID, and placebo. The co-primary endpoints of the study were PASI-75 (i.e. the proportion of treated subjects achieving a 75% reduction in their PASI score over baseline) and IGA score of 0 or1 at week 24.

At week 24 analysis, PASI-75 was achieved by 44.3%, 47.2% and 39.7% patients in PPC-06 600 mg BID, 400 mg BID and 400 mg QD treatment groups respectively, against 20% of patients in the placebo group ($p<0.05$). Additionally, 44.4%, 41.4% and 35.7% of patients in the PPC 06 600 mg BID and 400 mg BID and 400 mg QD groups, respectively, achieved an IGA

score of 0 or 1(IGA Clear) at week 24 against 22% of patients in the placebo group ($p<0.05$).

The most common adverse events (AE's) reported were lymphocytopenia, eosinophilia and gastrointestinal (GI) disorders, such as diarrhoea, nausea, abdominal pain and vomiting.

"Given the positive clinical data in this study, PPC-06 may have a potential to serve as an important therapeutic option for psoriasis patients in a market with limited oral treatments. We thank all the patients, investigators and study staff whose ongoing participation helped us achieve this target," said Sagar Munjal, MD, MS, Chief Medical Officer Promius Pharma/VP Clinical Development & Medical Affairs.