October 10, 2012

Press release

Mitsubishi Tanabe Pharma Corporation
KUREHA CORPORATION

Outcome of Global Phase III (EPPIC) Studies

Osaka and Tokyo, Japan, October 10, 2012—Mitsubishi Tanabe Pharma Corporation (President & Representative Director, CEO: Michihiro Tsuchiya) and KUREHA CORPORATION (President & CEO: Yutaka Kobayashi) announced today the completion of the AST-120, also known as MP-146 for Mitsubishi Tanabe Pharma development code, Global Phase III (EPPIC[*1]) Studies. AST-120 (Commercial name: Kremezin®) was innovated by KUREHA CORPORATION and has been under global development for treatment of chronic kidney disease (CKD) with its partner, Mitsubishi Tanabe Pharma Corporation.

Approximately 2,000 patients were enrolled in the studies which were conducted in Europe and the Americas[*2]. The studies were randomized, double-blind, placebo-controlled trials to evaluate the efficacy and tolerability of AST-120 at a dose of 9 g per day[*3]) added to standard-of-care therapy in patients with moderate to severe CKD. The primary endpoint was time to initiation of dialysis, kidney transplantation or doubling of serum creatinine.

Statistically-significant difference was not shown according to an analysis conducted on the primary endpoint. A subgroup analysis, however, suggested that AST-120 was effective in patients with factors associated with fast progressive CKD.
A safety profile was similar to placebo treated patients.

Additional details of the EPPIC study outcome will be presented in the American Society of Nephrology meeting scheduled on November 3, 2012.

*1: About the EPPIC studies:

Evaluating Prevention of Progression In Chronic Kidney Disease

KUREHA CORPORATION and Mitsubishi Tanabe Pharma Corporation executed a licensing agreement for global development of *"Kremezin®"* in patients with CKD and have conducted these multi-center studies which began in 2007.

Target population: moderate to severe CKD patients, approximately 2,000 patients

Countries: 13 countries in North America, Latin America and Europe

Centers: approximately 240 centers

Study period: 3.5 years

Study design: randomized, double-blind, placebo controlled

Efficacy endpoint

* Primary endpoint: time to initiation of dialysis, kidney transplantation or doubling of serum creatinine.
* Secondary endpoint: change of eGFR, etc.

*2: The patients enrolled in the EPPIC studies and the Japanese Phase III study differed in terms of the rate of CKD progression and serum creatinine levels required for study entry.

*3: The dosage of 9 g per day has not been approved in Japan (the approved dosage in Japan: 6 g)

About Kremezin®:

Kremezin® is an oral adsorbent consisting of highly purified spherical porous carbon. It adsorbs uremic toxins produced/secreted in the gastrointestinal tract and is eliminated in the feces, resulting in a reduced systemic absorption of uremic toxins and thereby an improvement in uremic symptoms and a delay in the initiation of dialysis. “Kremezin” has been marketed in Japan since 1991 as the world’s first medication for treatment of patients with CKD and has established its presence in this therapeutic area.

For further information:

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