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Kowa Pharma and Eli Lilly release PK study result

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Pharmacokinetic study evaluates interactions between LIVALO (pitavastatin) and Prezista/Norvir combination in healthy volunteers

Singapore: Kowa Pharmaceuticals and Eli Lilly released results from a pharmacokinetic (PK) study exploring potential drug interaction between the cholesterol medication pitavastatin (LIVALO) 4 mg and the protease inhibitor (PI) combination of darunavir/ritonavir (Prezista/Norvir) 800mg/100mg in healthy volunteers. In February 2012, the PK data darunavir/ritonavir were added to the LIVALO label. Kowa and Eli Lilly recently revealed results of a study comparing pitavastatin with pravastatin in lowering LDL-C.

Dr Craig Sponseller, VP, medical affairs, Kowa Pharmaceuticals, said that, "Examining drug interactions has been an ongoing part of product development, and we are pleased that results show no clinically significant drug interaction between pitavastatin and the protease inhibitor combination darunavir/ritonavir."

Pitavastatin and darunavir/ritonavir were co-administered in 28 healthy, adult volunteers over a 16-day period. When co-administered with darunavir/ritonavir, pitavastatin peak exposure, as measured by Cmax, decreased by four percent, while total exposure of pitavastatin, as measured by AUC0-Ï„, decreased by approximately 26 percent.

When co-administered with pitavastatin, the Cmax and AUC0-Ï„ of darunavir increased by six percent and three percent respectively, and the Cmax and AUC0-Ï„ of ritonavir increased by two percent and eight percent, respectively. These effects were not considered to be clinically significant.

A secondary objective of the study was to investigate the safety of pitavastatin and darunavir/ritonavir when each treatment was given alone or in combination. The majority of treatment emergent adverse events (TEAEs) were mild in severity, and no serious or severe adverse events were reported. Nineteen of 28 patients reported at least one TEAE, of which 10 were from the darunavir/ritonavir only group; seven from the pitavastatin and darunavir/ritonavir group; two from the pitavastatin only group. One subject was discontinued from the study due to maculopapular rash during treatment with darunavir/ritonavir only.