Arena and Eisai Announce Completion of Study Measuring Lorcaserin Concentrations in Human Cerebrospinal Fluid and Related Analyses

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SAN DIEGO and WOODCLIFF LAKE, N.J., Aug. 2, 2011 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (NASDAQ: ARNA [1]) and Eisai Inc. announced today the completion of a clinical study that measured lorcaserin concentrations in human cerebrospinal fluid (CSF) and plasma and related data analyses. The study was conducted to provide additional data that may be informative for determining the human relevance of the observation of brain astrocytoma in male rats. Using the results of this study and other preclinical and clinical studies, Arena estimates that the mean exposure of the human brain to lorcaserin at the clinically tested dose (10 mg dosed twice daily (BID)) is approximately 1.7 times the exposure in the human plasma. In contrast, the measured exposure of the male rat brain to lorcaserin at the dose at which no brain astrocytoma was observed (10 mg/kg/day) is approximately 24 times the exposure in the rat plasma.

"We estimate that humans concentrate lorcaserin in the brain to a much lower extent than do rats," said William R. Shanahan, M.D., Arena's Senior Vice President and Chief Medical Officer. "We believe these results may be helpful in assessing the human relevance of the observation of brain astrocytoma in the rat carcinogenicity study."

This study is one of the activities intended to address the observation of brain astrocytoma in male rats as part of the overall plan to submit a response to the lorcaserin Complete Response Letter (CRL). Activities intended to address the observation of mammary adenocarcinoma in female rats and other issues identified by the US Food and Drug Administration (FDA) are ongoing.

Study Rationale, Design and Related AnalysesBrain astrocytoma was observed in male rats given certain doses of lorcaserin during a two-year carcinogenicity study. One approach to estimating a safety margin for this finding would be to use plasm
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