PARI Pharma's Altera Delivers Gilead's Cayston in Head-to-Head Study With Tobramycin Inhalation Solution

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MONTEREY, Calif., June 21 /PRNewswire/ -- In a head-to-head, Phase III clinical trial of Cayston delivered by the Altera Nebulizer System versus tobramycin inhalation solution in cystic fibrosis patients with *Pseudomonas aeruginosa*, the co-primary endpoint of non-inferiority for mean percent change in forced expiratory volume in one second (FEV(1)) percent predicted after 28 days of treatment was achieved. Patients receiving Cayston had a mean increase in FEV(1) percent predicted from baseline to day 28 of 8.35 percent compared to 0.55 percent for patients receiving tobramycin inhalation solution, meeting the statistical definition of superiority for the Cayston and Altera combination. Safety results were similar across both arms of the study, with lower incidence of cough in patients receiving Cayston. This data was presented by Gilead Sciences during a late-breaker oral session on Friday at the 33rd European Cystic Fibrosis Conference (ECFC).

In the study, 268 patients were randomized to receive Cayston or tobramycin inhalation solution over a 24-week treatment period. Approximately 85 percent of patients in the study had received at least three courses of inhaled tobramycin in the 12 months prior to randomization. Final six-month study results will become available for presentation later this year.

"We are very pleased to see these encouraging results. Our goal is to improve therapies for respiratory care using our advanced aerosol delivery platforms, such as eFlow Technology. In addition to aerosol delivery expertise, PARI Pharma also contributed to the initial formulation of Cayston and optimized the formulation to the Altera Nebulizer System. As evidenced in multiple clinical trials, Altera delivers Cayston in two to three minutes – a significant reduc '/>"/>

SOURCE [1]

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