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Novartis COPD trial meets primary endpoint

30 August 2012 | News | By BioSpectrum Bureau

Novartis QVA149 phase III study meets primary endpoint

Singapore: The fifth QVA149 (indacaterol maleate / glycopyrronium bromide) phase III study of Novartis, SPARK, met its primary endpoint of a reduced rate of moderate-to-severe COPD exacerbations compared to glycopyrronium bromide. SPARK is the final study intended for initial regulatory filings of QVA149 in Europe and Japan, which are expected in Q4 2012. The US filing of QVA149 is expected at the end of 2014.

"We are very pleased that SPARK showed a reduction of exacerbations, further demonstrating that QVA149 could improve the lives of patients with COPD," said Mr Tim Wright, head of Development, Novartis Pharmaceuticals. "We are looking forward to filing QVA149 initially in Europe and Japan, which will bring us another step closer to providing a full range of innovative COPD medicines to help physicians select the right treatment for the right patient at the right time."

SPARK met its primary endpoint by demonstrating that patients treated with once-daily investigational QVA149 for 64 weeks demonstrated a clinically meaningful and statistically significant lower rate of moderate-to-severe COPD exacerbations compared to patients treated with once-daily glycopyrronium 50 mcg. The study also showed that the rate of moderate-to-severe exacerbations was numerically lower in patients on QVA149 compared to open-label tiotropium 18 mcg.

QVA149 is an investigational inhaled, once-daily, fixed-dose combination of the long-acting beta2-adrenergicagonist indacaterol maleate, and the investigational long-acting muscarinic antagonist glycopyrronium bromide, being investigated for the treatment of COPD in the phase III IGNITE clinical trial program. IGNITE is one of the largest international clinical trial programs in COPD comprising 10 studies in total with more than 7,000 patients across 42 countries.