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Novartis announces positive results in COPD portfolio trials

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Singapore: Data from the once-daily chronic obstructive pulmonary disease (COPD) clinical trial programs were presented by Novartis at the European Respiratory Society (ERS) Congress. Overall, Novartis presented 14 abstracts, including data from the investigational QVA149 IGNITE phase III clinical trial program, and the glycopyrronium bromide GLOW phase III clinical trial program.

Among the data presented, three new studies from the investigational QVA149 IGNITE phase III clinical trial program

demonstrated that QVA149 significantly improved lung function compared to other COPD therapies. QVA149 is an inhaled fixed dose combination product for the treatment of COPD. The product combines NVA237, the long acting muscarinic antagonist (LAMA), licensed by Sosei Group to Novartis, together with Novartis' long acting beta agonist (LABA), indacaterol, now approved in more than 80 countries, including EU, Japan and the USA. Novartis are responsible for the development and commercialization of this product.

Data from the GLOW program showed that glycopyrronium 50 mcg once daily provided rapid and sustained bronchodilation, and reduced exacerbations and symptoms when compared to placebo, similar to the levels observed with open-label (OL) tiotropium 18 mcg. IGNITE data demonstrated the efficacy of the dual-bronchodilator QVA149 and showed a superior effect on lung function and patient-reported outcomes versus comparators. SHINE met its primary endpoint by demonstrating that once-daily QVA149 110/50 mcg improved lung function as measured by trough FEV1 compared to once-daily indacaterol maleate 150 mcg and once-daily glycopyrronium 50 mcg.

QVA149 110/50 mcg is an investigational inhaled dry-powder fixed-dose combination medication that provides the equivalent amount of indacaterol as Onbrez 150 mcg along with glycopyrronium 50 mcg.

"We are very excited that the Novartis data at ERS brings us one step further to delivering on the promise to provide COPD patients and physicians with a range of innovative treatments," said Mr David Epstein, head of Novartis Pharmaceuticals. "These products are all being made available in the Breezhaler device which allows patients to hear, feel and see that they have taken the drug correctly."

Sosei CEO Shinichi Tamura commented, "We are very encouraged by the substantial body of GLOW and IGNITE data presented at the European Respiratory Society meeting and look forward to the approval of glycopyrronium bromide in Europe and the filing of QVA149 in Europe and Japan."