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ASIA EDITION

Japan approves AstraZeneca's Tezspire for severe asthma treatment

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Tezspire approved for a broad population of patients with severe asthma with no phenotype or biomarkerlimitations

AstraZeneca's *Tezspire* (tezepelumab) has been approved in Japan for the treatment of bronchial asthma in patients with severe or refractory disease in whom asthma symptoms cannot be controlled with mid- or high-dose inhaled corticosteroids and other long-term maintenance therapies.

The approval by the Japanese Ministry of Health, Labour and Welfare (MHLW) was based on efficacy and safety results from the PATHFINDER clinical trial programme. The application included results from the pivotal NAVIGATOR Phase III trial in which *Tezspire* demonstrated superiority across every primary and key secondary endpoint in patients with severe asthma, compared to placebo, when added to standard therapy.

Tezspire is the first and only biologic for severe asthma that acts at the top of the inflammatory cascade by blocking thymic stromal lymphopoietin (TSLP), an epithelial cytokine. *Tezspire*consistently and significantly reduced asthma exacerbations across the PATHWAY Phase II and NAVIGATOR Phase III clinical trials which included a broad population of severe asthma patients irrespective of key biomarkers, including blood eosinophil counts, allergic status and fractional exhaled nitric oxide (FeNO).

Tezspire is approved in the US, the EU and other countries for the treatment of severe asthma. Other regulatory reviews evaluating *Tezspire* are ongoing in several markets around the world.