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GSK announces positive phase III results from ANCHOR trials for depemokimab in chronic rhinosinusitis with nasal polyps

- Primary endpoints met with statistically significant reduction in nasal polyp size and nasal obstruction versus placebo plus standard of care, at 52 weeks
- Depemokimab is an ultra-long-acting biologic administered once every six months
- Patients with chronic rhinosinusitis with nasal polyps (CRSwNP) experience a range of symptoms which are widely underestimated and often sub-optimally treated

GSK plc (LSE/NYSE: GSK) today announced positive headline results from the phase III clinical trials ANCHOR-1 and ANCHOR-2, which assessed the efficacy and safety of depemokimab versus placebo in adults with CRSwNP. Both trials met their co-primary endpoints of a change from baseline in total endoscopic nasal polyp score at 52 weeks and change from baseline in mean nasal obstruction score from weeks 49 to 52. The overall incidence and severity of treatment-emergent adverse events across both trials were similar in patients treated with either depemokimab or placebo. Further analysis of these data is ongoing. The full results of ANCHOR-1 and ANCHOR-2 will be presented at an upcoming scientific congress.

Kaivan Khavandi, SVP, Global Head of Respiratory/Immunology R&D at GSK, said: “Globally millions of people suffer from uncontrolled CRSwNP, the majority of whom will exhibit markers of type 2 inflammation. These patients have high corticosteroid exposure and often experience recurrence of nasal polyps following surgery. We're very encouraged by the results from the ANCHOR studies, which demonstrate the potential for depemokimab to offer targeted and sustained suppression of a key inflammatory pathway underlying nasal polyp growth and nasal obstruction. Today’s data, along with recent phase III data in severe asthma, will be used in regulatory filings around the world."

Depemokimab is the first ultra-long-acting biologic to be evaluated in phase III trials with an extended half-life and high binding affinity and potency for interleukin-5 (IL-5), which could enable dosing once every six-months for patients with CRSwNP.[1-3] IL-5 is present at high levels in nasal polyp tissue and is a key cytokine (protein) in type 2 inflammation.[1,4-7]

These data are part of GSK’s aspirations to advance treatment goals for those with type 2 inflammatory conditions like CRSwNP. Being able to deliver sustained suppression of inflammation that drives the disease and its progression, has the potential to benefit patients and clinicians by reducing the risk of inflammation reoccurring due to missed doses. Increased dosing intervals may also reduce the need for regular clinic time.

CRSwNP is a chronic condition that affects up to 4% of the general population, of whom 40% have uncontrolled disease.[8,9] It is caused by inflammation of the nasal lining that can lead to soft tissue growths, known as nasal polyps.[4,10] People with CRSwNP experience symptoms such as nasal obstruction, loss of smell, facial pressure, sleep disturbance, infections and nasal discharge that can significantly affect their emotional and physical well-being.[4,10]

Up to 80% of people with CRSwNP show evidence of type 2 airway inflammation, typically detected by blood eosinophil count as a biomarker, which is associated with more severe disease and symptoms.[4-7,11]These patients are likely to have a history of sinonasal surgery, which is accompanied by a high risk of nasal polyp recurrence and have high OCS use that is known to be associated with severe complications.[7,10,11]

Data from ANCHOR-1 and ANCHOR-2 along with data from SWIFT-1 and SWIFT-2, the phase III trials of depemokimab in severe asthma, will be used in regulatory filings around the world. Depemokimab is currently not approved anywhere.

About ANCHOR-1 and ANCHOR-2[1,2]
ANCHOR-1 and ANCHOR-2 were replicate phase III clinical trials assessing the safety and efficacy of depemokimab in patients with CRSwNP. Both were 52-week, randomised, double-blind, parallel group, placebo controlled, multi-centre trials. Number of subjects included in the Full Analysis Set of ANCHOR-1: depemokimab = 143, placebo = 128 and in ANCHOR-2: depemokimab = 129, placebo = 128.

About the depemokimab development programme
Depemokimab's extended half-life, high potency and high binding affinity for IL-5 means it has the potential to provide sustained inhibition of broad inflammatory functions with dosing once every six-months. The phase III programme includes evaluation of depemokimab in other IL-5 mediated diseases. These include severe asthma,[3,13,14] eosinophilic granulomatosis with polyangiitis (EGPA)[14] and hypereosinophilic syndrome (HES).[15] The first phase III trials in severe asthma, SWIFT-1 and SWIFT-2, have been reported and published in the *New England Journal of Medicine.*[3]

GSK in respiratory
GSK continues to build on decades of pioneering work to deliver more ambitious treatment goals, develop the next generation standard of care, and redefine the future of respiratory medicine for hundreds of millions of people with respiratory diseases. With an industry-leading respiratory portfolio and pipeline of vaccines, targeted biologics, and inhaled medicines, we are focused on improving outcomes and the lives of people living with all types of asthma and COPD along with less understood refractory chronic cough or rarer conditions like systemic sclerosis with interstitial lung disease. GSK is harnessing the latest science and technology with the aim to modify underlying disease dysfunction and prevent disease progression.

About GSK
GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

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