Stock-exchange announcement

For media and investors only

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GSK's *Nucala* (mepolizumab) approved in China for treatment of adults with chronic rhinosinusitis with nasal polyps

- Mepolizumab is the only anti-interleukin-5 approved in China for the treatment of adults with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)
- Around 30 million people in China live with CRSwNP and experience symptoms such as sleep disturbance, breathing problems and loss of smell
- This is the third indication for mepolizumab in China for an IL-5 mediated condition

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GSK plc (LSE/NYSE: GSK) today announced that the China National Medical Products Administration has approved *Nucala* (mepolizumab), a monoclonal antibody that targets interleukin-5 (IL-5), as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

Kaivan Khavandi, SVP, Global Head of Respiratory/Immunology R&D at GSK said: "We are delighted that *Nucala* has been approved in China as a treatment for CRSwNP, a chronic condition for which new and effective treatments are needed. Patients now have a non-surgical option available to them and an alternative to repeated exposure to oral corticosteroids."

It is estimated that about 107 million people in China suffer from chronic sinusitis, about 1/3 of whom have chronic sinusitis with nasal polyps.[1-4] People with CRSwNP experience symptoms such as nasal obstruction, loss of smell, facial pressure, sleep disturbance and nasal discharge, which can significantly affect their emotional and physical well-being.[4-6]

CRSwNP is caused by chronic inflammation of the nasal lining that can cause soft tissue growth, known as nasal polyps, that develop in the sinuses and nasal cavity.[5,6] Up to 80% of patients with CRSwNP have type 2 inflammation, which is associated with more severe disease and nasal polyp recurrence and can be detected by blood eosinophil count, a biomarker measured by a simple blood test.[6-9] IL-5 is a key cytokine driving this type 2 inflammation and is present at high levels in nasal polyp tissue.[4-8] Although surgery can be effective at removing polyps, the underlying type 2 inflammation means they have a tendency to regrow.[9,10]

The approval is based on results of the phase III MERIT trial, which studied the efficacy and safety of mepolizumab over a 52-week period versus placebo in a population of Japanese, Chinese and Russian patients with inadequately controlled CRSwNP, and is supported by data from the global phase III SYNAPSE study, which explored the effect of mepolizumab versus placebo in more than 400 patients with CRSwNP.[5,10]

Mepolizumab is already approved in China as an add-on maintenance treatment for adults and adolescents aged 12 years and older with severe eosinophilic asthma as well as for adults with eosinophilic granulomatosis with polyangiitis.

About the MERIT trial[10]

The MERIT trial was a randomised, double-blind, placebo-controlled, parallel-group, 52-week Phase III study to assess the efficacy and safety of mepolizumab in patients with chronic rhinosinusitis with nasal polyps (CRSwNP)/eosinophilic CRS (ECRS) in Japan, Russia, and China. The co-primary endpoints were change from baseline in nasal obstruction visual analogue scale (VAS) score during weeks 49 to 52 compared with placebo and change in endoscopic nasal polyp score at week 52 compared with placebo. Results from 163 participants (mepolizumab =80, placebo = 83) showed that treatment with mepolizumab significantly improved nasal

obstruction VAS score (mean treatment difference: -1.43 [95% CI: -2.37, -0.50]; p=0.003) and was associated with a numerical reduction in nasal polyp score at week 52 (-0.43 [-0.89, 0.03]; p=0.067). Improvements in patient quality of life, as measured by the 22-item Sino-Nasal Outcome Test (SNOT-22) were demonstrated with mepolizumab versus placebo at Week 52 (difference: -10.63 [-18.68, -2.57]; p=0.01 and loss of smell VAS score at Weeks 49–52 (difference: -0.82 [-1.43, -0.21]; p=0.009). Safety and tolerability data were consistent with the known profile of mepolizumab.[4,9-11] A similar proportion of patients experienced on-treatment adverse events in the mepolizumab (68/84 [81%]) and placebo (65/85 [76%]) groups. In total, seven patients had treatment-related adverse events (five in the placebo group and two in the mepolizumab group); none of these were severe adverse events.

About *Nucala* (mepolizumab)
First approved in 2015 for severe asthma with an eosinophilic phenotype in the US, mepolizumab is a monoclonal antibody that binds directly to and inhibits interleukin-5 (IL-5), a key messenger protein (cytokine) in type 2 inflammation.[11,12] Mepolizumab has been developed for the treatment of a range of IL-5 mediated diseases associated with type 2 inflammation.[10,11]

For product and important safety information please consult the country relevant summary of product characteristics.

EU and UK available at:
https://www.ema.europa.eu/en/documents/product-information/nucala-epar-product-information_en.pdf

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.

GSK enquiries

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Dan Smith / Sarah Clements	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Lyndsay Meyer	+1 202 302 4595	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Annabel Brownrigg-Gleeson	+44 (0) 7901 101944	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Camilla Campbell	+44 (0) 7803 050238	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)

Cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2023, and GSK's Q3 Results for 2024.

Registered in England & Wales:
No. 3888792

Registered Office:
79 New Oxford Street
London
WC1A 1DG

References

1. Liu Z, et al. Chinese Society of Allergy and Chinese Society of Otorhinolaryngology-Head and Neck Surgery Guideline for Chronic Rhinosinusitis. *Allergy Asthma Immunol Res*. 2020;12(2):176-237.
2. Wu Q, et al. Efficacy and safety of omalizumab in chronic rhinosinusitis with nasal polyps: a systematic review and meta-analysis of randomised controlled trials. BMJ Open. 2021 Sep;11(9):e047344.
3. Bachert C, et al. Burden of Disease in Chronic Rhinosinusitis with Nasal Polyps. *J Asthma Allergy*. 2021;14:127-134.
4. Wang Chengshuo, Zhang Luo. Biologics for the treatment of chronic rhinosinusitis with nasal polyps [J] . Chinese Journal of Otolaryngology-Head and Neck Surgery, 2023, 58(3) : 193-199.
5. Han JK, et al. Mepolizumab for chronic rhinosinusitis with nasal polyps (SYNAPSE): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Respir Med.* 2021;9(10):1141-1153.
6. Bachert C, et al. EUFOREA expert board meeting on uncontrolled severe chronic rhinosinusitis with nasal polyps (CRSwNP) and biologics: Definitions and management. *J Allergy Clin Immunol*. 2021;147(1):29-36.
7. Kato A, et al. Endotypes of chronic rhinosinusitis: Relationships to disease phenotypes, pathogenesis, clinical findings, and treatment approaches. *Allergy*. 2022;77(3):812-826.
8. De Corso E, et al. How to manage recurrences after surgery in CRSwNP patients in the biologic era: a narrative review. *Acta Otorhinolaryngol Ital*. 2023;43(2 Suppl. 1):S3-S13.
9. Chen S, et al. Systematic literature review of the epidemiology and clinical burden of chronic rhinosinusitis with nasal polyposis. *Curr Med Res Opin.* 2020;36(11):1897-1911.
10. Fujieda S, et al. Mepolizumab in CRSwNP/ECRS and NP: The Phase III randomised MERIT trial in Japan, China and Russia. *Rhinology.* 26 July 2024. doi: 10.4193/Rhin24.156. Online ahead of print.
11. U.S. Food and Drug Administration. *Nucala* Full Prescribing Information. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761122s000lbl.pdf. Last accessed October 2024
12. European summary of product characteristics available at https://www.ema.europa.eu/en/documents/product-information/nucala-epar-product-information_en.pdf Last accessed December 2024