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ASIA EDITION

Japan approves GSK's Arexvy, country's first RSV vaccine for adults

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The approval – the first in Asia – is based on a comprehensive phase III programme, which enrolled over 1,000 Japanese participants

British pharma firm GlaxoSmithKline (GSK) has announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved Arexvy (respiratory syncytial virus vaccine, recombinant adjuvanted) for the prevention of RSV (respiratory syncytial virus) disease for adults 60 years of age and above. This is the first time an RSV vaccine for older adults has been approved in Japan.

RSV is a common, contagious respiratory virus that causes an estimated 470,000 hospitalisations and 33,000 deaths each year in adults 60 years of age and older in industrialised countries, including approximately 63,000 hospitalisations and 4,500 deaths in Japan. Its impact on healthcare systems may further increase as the population ages. Those with underlying medical conditions, such as chronic heart disease, chronic lung disease or diabetes, account for the majority of RSV hospitalisations.

The approval has been granted based on data from the pivotal AReSVi-006 (Adult Respiratory Syncytial Virus) phase III vaccine efficacy trial, published in the New England Journal of Medicine. In the trial, the vaccine showed statistically significant and clinically meaningful overall efficacy of 82.6% (96.95% CI, 57.9–94.1, 7 of 12,466 in the Arexvy arm vs 40 of

12,494 in the placebo arm) against RSV-LRTD in adults aged 60 years and older, meeting the primary endpoint. In addition, secondary descriptive endpoints show that efficacy was 94.6% (95% CI, 65.9–99.9, 1 of 4,937 in the Arexvy arm vs 18 of 4,861 in the placebo arm) in older adults with at least one underlying medical condition of interest, such as certain cardiorespiratory and endocrine-metabolic conditions.

The vaccine was generally well tolerated. The most frequently observed solicited adverse events were injection site pain, fatigue, myalgia, headache and arthralgia. These were generally mild to moderate and transient.