Press Release

For media and investors only

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GSK announces positive topline data on co-administration of AREXVY and SHINGRIX

- Trial met primary endpoint, non-inferior immune response for both vaccines when co-administered compared with separate administration
- Co-administration of the RSV and shingles adjuvanted vaccines was well -tolerated, with acceptable reactogenicity and safety profiles
- These data advance the science of co-administration of recommended adult vaccines

GSK plc (LSE/NYSE: GSK) today announced positive topline data from the phase 3 trial in adults 50 years and older evaluating the immunogenicity, reactogenicity and safety of AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) when co-administered with SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted), both AS01-adjuvanted vaccines (NCT05966090).[1,2] The data were presented as a late-breaking abstract at the European Geriatric Medicine Society (EuGMS) Congress in Valencia, Spain (September 18-20th, 2024).[2] SHINGRIX is approved for the prevention of shingles (herpes zoster) in adults aged 50 years and older. AREXVY is approved for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older, as well as individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.

The data showed a non-inferior immune response when the vaccines were co-administered compared to when they were administered at separate visits.[2] Co-administration was also well tolerated, with acceptable reactogenicity and safety profiles.[2] In both groups, the most frequently reported adverse events were pain at the injection site, fatigue, and myalgia.[2] The duration of solicited adverse events was comparable across the two groups.[2]

Len Friedland, MD, Vice President of Scientific Affairs and Public Health, GSK, said: "We are excited to share data on the co-administration of our RSV and shingles vaccines. Adult immunization offers immense individual and societal benefits and yet, vaccination rates for adults are often inadequate. With our co-administration studies, GSK is using its science and technology to help remove barriers to adult immunization, by potentially reducing the number of visits to the healthcare offices and pharmacies and ultimately help to get ahead of RSV and shingles."

Results from this trial will be submitted for peer-reviewed scientific publication and will be used to support regulatory submissions to the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other regulators.

Both RSV and shingles pose significant health risks to older adults, and these risks only increase with age as the immune system declines. Immunocompromised individuals and those with certain underlying medical conditions—for example, asthma and COPD—may also be at increased risk for these diseases.[3,4,5] RSV is a common, contagious respiratory virus that can lead to potentially serious respiratory illness.[3] Each year, approximately 177,000 adults 65 years and older are hospitalized in the US due to RSV and an estimated 14,000 of those cases result in death.[6] Shingles is a painful, blistering rash that can last for weeks. Because it is caused by the reactivation of the varicella zoster virus (VZV) – the same virus that causes chickenpox, 99% of US adults have the virus that causes shingles inside their body, although not everyone will develop shingles.[7] An estimated one million people develop shingles annually in the US.[8]

About AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted)
AREXVY contains recombinant RSV glycoprotein F stabilised in the prefusion conformation (RSVPreF3). This antigen is combined with GSK's proprietary AS01E adjuvant. The vaccine has been approved for the prevention of

RSV-LRTD in individuals 60 years of age and older in 50 countries, including Europe, Japan and US. It is also approved in several countries for use in adults aged 50–59 at increased risk for RSV-LRTD, including European Union/European Economic Area and US. Regulatory reviews in multiple countries are ongoing. The proposed trade name remains subject to regulatory approval in other markets.

The GSK proprietary AS01 adjuvant system contains QS-21 STIMULON adjuvant licensed from Antigenics Inc, a wholly owned subsidiary of Agenus Inc.

Indication for AREXVY
AREXVY is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in:

- Individuals 60 years of age and older;
- Individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.

Important Safety Information for AREXVY
- AREXVY is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of AREXVY.
- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of AREXVY.
- Syncope (fainting) may occur in association with administration of injectable vaccines, including AREXVY. Procedures should be in place to avoid injury from fainting.
- Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to AREXVY.
- In adults 60 years of age and older, the most commonly reported adverse reactions (≥10%) were injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%).
- In adults 50 through 59 years of age, the most commonly reported adverse reactions (≥10%) were injection site pain (75.8%), fatigue (39.8%), myalgia (35.6%), headache (31.7%), arthralgia (23.4%), erythema. (13.2%), and swelling (10.4%).
- There are no data on the use of AREXVY in pregnant or breastfeeding individuals. AREXVY is not approved for use in persons <50 years of age.
- Vaccination with AREXVY may not result in protection of all vaccine recipients.

Please see full **Prescribing Information** for AREXVY.

About SHINGRIX (Recombinant Zoster Vaccine or RZV)
SHINGRIX is a non-live, recombinant subunit vaccine indicated for the prevention of shingles in adults 50 and over. It combines an antigen, glycoprotein E, with an adjuvant system, AS01$_B$, and may help overcome the natural age-related decline in responses to immunization that contributes to the challenge of protecting adults aged 50 and over from shingles.[9,10] RZV is not indicated to prevent primary varicella infection (chickenpox). In several countries, it is also approved for adults aged 18 years or over at increased risk for shingles. The use of RZV should be in accordance with official recommendations and local product label.

Indication for SHINGRIX
SHINGRIX is an FDA-approved vaccine for the prevention of shingles (herpes zoster) in:

- Adults 50 years and older.
- Adults 18 years and older who are or will be at increased risk of shingles due to being immunocompromised by known disease or therapy.

SHINGRIX is not used to prevent chickenpox.

Important Safety Information for SHINGRIX
- SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX.

- Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.
- In a post marketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with SHINGRIX.
- Syncope (fainting) can be associated with the administration of vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.
- In individuals aged 50 years and older: Solicited local adverse reactions were pain, redness, and swelling. Solicited general adverse reactions were myalgia, fatigue, headache, shivering, fever, and gastrointestinal symptoms.
- The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women.
- It is not known whether Shingrix is excreted in human milk. Data are not available to assess the effects of Shingrix on the breastfed infant or on milk production/excretion.
- Vaccination with SHINGRIX may not result in protection of all vaccine recipients.

Please see full **Prescribing Information** for SHINGRIX.

About the NCT05966090 trial
The co-administration study is a phase 3, open-label, multi-country study to assess non-inferiority of immune responses in co-administration of GSK's RSV and Recombinant Zoster Vaccine (RZV) compared to separate administration in adults aged 50 and over.[2]

530 participants were randomized 1:1 to receive either GSK's Recombinant Zoster Virus vaccine first dose and GSK's Respiratory Syncytial Virus, Adjuvanted at visit one (Co-ad), or GSK's Recombinant Zoster Virus vaccine first dose alone at visit one (Control). The Control group received GSK's RSV vaccine at day 31.[1,2] RZV second dose was administered at day 61 for both groups.[1,2] The primary endpoint was the non-inferiority of the humoral immune responses to GSK's RSV vaccine and RZV when co-administered compared to when administered at separate visits.[1,2] Key secondary endpoints included reactogenicity and safety following co-administration versus sequential administration of GSK's RSV vaccine and RZV.[1,2]

Anti-gE antibody concentrations and RSV-A and RSV-B neutralization titers increased from pre- to post-vaccination and met the non-inferiority criteria in the primary endpoint for the humoral immune responses to GSK's RSV and shingles vaccines.[2] In both groups, the duration of solicited adverse events was short and comparable, and the most frequently reported adverse events were pain at the injection site, fatigue, and myalgia.[2] Unsolicited adverse events reporting rates were balanced between the co-administration and control groups.[2]

About RSV in Adults
RSV is a common, contagious respiratory virus affecting the lungs and breathing passages.[3] Adults can be at increased risk for RSV disease due to certain underlying medical conditions, immune compromised status, or advanced age.[3] RSV can exacerbate conditions, including COPD, asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalization, and death.[3]

About Shingles
Shingles is caused by the reactivation of the varicella-zoster virus (VZV), the same virus that causes chickenpox.[11] By age 50, VZV is present in most adults[12] and may reactivate with advancing age.[13] As people age, the strength of the immune system response to infection wanes, increasing the risk of developing shingles.[11] Shingles typically presents as a rash, with painful blisters across the chest, abdomen, or face.[11] The pain is often described as aching, burning, stabbing or shock-like.[14] Following the rash, a person may experience post-herpetic neuralgia (PHN), a long-lasting nerve pain that can last weeks or months and occasionally persists for several years.[14] PHN is the most common complication of shingles, occurring in 5–30% of all shingles cases from findings in various studies.[15]

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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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 Q2 Results for 2024.

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