GSK

Press release

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GSK's older adult respiratory syncytial virus (RSV) vaccine candidate shows 94.1% reduction in severe RSV disease and overall vaccine efficacy of 82.6% in pivotal trial

- Data to be presented at IDWeek 2022 showed overall vaccine efficacy against RSV-lower respiratory tract disease (LRTD) in adults aged 60 years and above, with a favourable safety profile
- Consistent high vaccine efficacy observed against LRTD in severe disease (94.1%), adults aged 70-79 years (93.8%) and in adults with underlying comorbidities (94.6%)
- High vaccine efficacy is consistent across RSV A and B strains

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GSK plc (LSE/NYSE: GSK) today announced positive pivotal phase III trial results for its respiratory syncytial virus (RSV) vaccine candidate for adults aged 60 years and above to be presented at IDWeek 2022. The vaccine candidate was highly efficacious, demonstrating overall vaccine efficacy of 82.6% (96.95% CI, 57.9–94.1, 7 of 12,466 vs. 40 of 12,494) against RSV lower respiratory tract disease (RSV-LRTD), meeting the trial's primary endpoint.

Consistent high vaccine efficacy was also observed across a range of pre-specified secondary endpoints, highlighting the impact the vaccine candidate could have on the populations most at risk of the severe outcomes of RSV. Efficacy against severe RSV-LRTD, defined as LRTD with at least two lower respiratory signs or assessed as severe by the investigator and confirmed by the external adjudication committee, was 94.1% (95% CI, 62.4–99.9, 1 of 12,466 vs. 17 of 12,494). In participants with pre-existing comorbidities, such as underlying cardiorespiratory and endocrinometabolic conditions, vaccine efficacy was 94.6% (95% CI, 65.9–99.9, 1 of 4,937 vs. 18 of 4,861), with 93.8% (95% CI, 60.2-99.9, 1 of 4,487 vs. 16 of 4,487) efficacy observed in adults aged 70-79 years.

Vaccine efficacy against LRTD was consistent across both RSV-A and RSV-B subtypes (84.6%; CI 32.1–98.3, 2 of 12,466 vs. 13 of 12,494 and 80.9%; CI 49.4–94.3, 5 of 12,466 vs. 26 of 12,494 respectively), consistent with the robust neutralising antibody response generated against both subtypes. See Figure 1: Vaccine efficacy against first episodes of RSV-confirmed LRTD and RSV-confirmed ARI (modified exposed set).

Tony Wood, GSK Chief Scientific Officer, said: "These are truly exceptional results given that today RSV remains one of the major infectious diseases without a vaccine, despite over 60 years of research. We believe that with the high vaccine efficacy demonstrated in this pivotal trial, our vaccine candidate has the potential to help reduce the significant global burden of RSV-associated disease in older adults, including those at the greatest risk of severe outcomes due to their age or underlying comorbidities."

The vaccine was well tolerated with a favourable safety profile. The observed solicited adverse events were typically mild-to-moderate and transient, the most frequent being injection site pain, fatigue, myalgia, and headache.

Regulatory submissions based on the phase III data are anticipated in the second half of 2022. GSK's RSV vaccine candidate for older adults contains a recombinant subunit prefusion RSV F glycoprotein antigen (RSVPreF3) combined with GSK's proprietary AS01$_E$ adjuvant. There are currently no RSV vaccines approved anywhere in the world.

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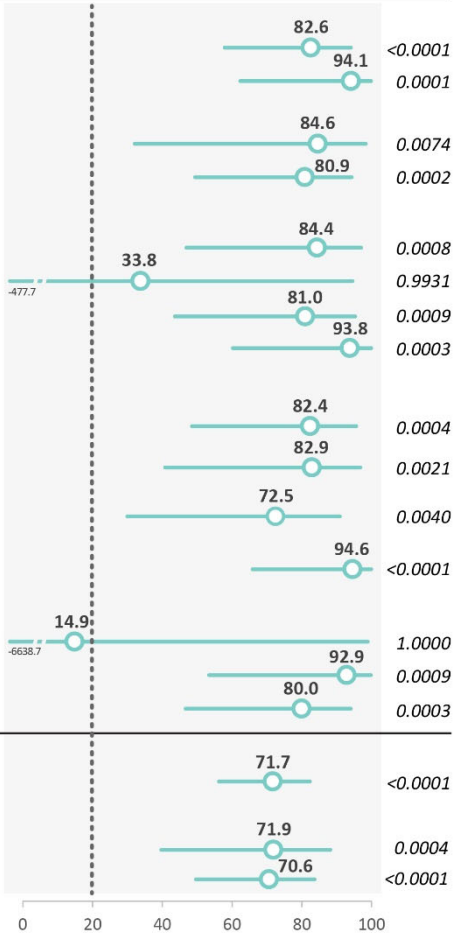
Figure 1. Vaccine efficacy against first episodes of RSV-confirmed LRTD and RSV-confirmed ARI (modified exposed set)

	RSVPreF3 OA				Placebo					
	N	n	T (p-yr)	n/T (n/1000 p-yr)	N	n	T (p-yr)	n/T (n/1000 p-yr)	Vaccine efficacy (%)	*p-value*[a]
RSV-confirmed LRTD										
Overall	12466	7	6865.9	1.0	12494	40	6857.3	5.8	82.6	*<0.0001*
Severe	12466	1	6867.9	0.1	12494	17	6867.7	2.5	94.1	*0.0001*
By subtype										
RSV-A	12466	2	6867.4	0.3	12494	13	6868.9	1.9	84.6	*0.0074*
RSV-B	12466	5	6866.7	0.7	12494	26	6862.3	3.8	80.9	*0.0002*
By age										
≥70 yr	5503	3	3015.0	1.0	5515	19	3020.9	6.3	84.4	*0.0008*
≥80 yr	1016	2	551.4	3.6	1028	3	559.3	5.4	33.8 (-477.7)	*0.9931*
60–69 yr	6963	4	3850.8	1.0	6979	21	3836.4	5.5	81.0	*0.0009*
70–79 yr	4487	1	2463.6	0.4	4487	16	2461.6	6.5	93.8	*0.0003*
By baseline comorbidities										
Low/medium risk[b]	8235	4	4495.8	0.9	8367	23	4560.6	5.0	82.4	*0.0004*
High risk[b]	4231	3	2370.0	1.3	4127	17	2296.6	7.4	82.9	*0.0021*
No comorbidity of interest[c]	7529	6	4094.1	1.5	7633	22	4148.1	5.3	72.5	*0.0040*
≥1 comorbidity of interest[c]	4937	1	2771.8	0.4	4861	18	2709.1	6.6	94.6	*<0.0001*
By frailty[d]										
Frail	189	1	95.8	10.4	177	1	92.9	10.8	14.9 (-6638.7)	*1.0000*
Pre-frail	4792	1	2577.6	0.4	4778	14	2545.3	5.5	92.9	*0.0009*
Fit	7464	5	4182.7	1.2	7519	25	4208.5	5.9	80.0	*0.0003*
RSV-confirmed ARI										
Overall	12466	27	6858.7	3.9	12494	95	6837.8	13.9	71.7	*<0.0001*
By RSV subtype										
RSV-A	12466	9	6865.2	1.3	12494	32	6862.3	4.7	71.9	*0.0004*
RSV-B	12466	18	6861.7	2.6	12494	61	6849.4	8.9	70.6	*<0.0001*



Cases reported up to the efficacy data lock point of 11 April 2022. **N**, number of participants in the modified exposed set; **n**, number of participants with ≥1 RSV-confirmed LRTD (identified by the adjudication committee) or ≥1 RSV-confirmed ARI; **T**, sum of follow-up time (from day 15 post-vaccination until first occurrence of the event, data lock point or drop-out); **p-yr**, person-years; **n/T**, incidence rate of participants reporting at least one event. Error bars represent 96.95% confidence intervals (CI) for primary objective (RSV-confirmed LRTD, overall) and 95% CI for other endpoints. [a]Two-sided exact p-value conditional to number of cases comparing incidence rates. [b]Charlson comorbidity index: low/medium risk, participants with baseline comorbidity score ≤3; high risk, participants with baseline comorbidity score >3. [c]Comorbidities of interest included chronic obstructive pulmonary disease, asthma, any chronic respiratory/pulmonary disease, chronic heart failure, diabetes mellitus type 1 or type 2 and advanced liver or renal disease. [d]Frailty status assessed using a gait speed test: frail, participants with a walking speed <0.4 m/s or not able to perform the test; pre-frail, participants with a walking speed of 0.4–0.99 m/s; fit, participants with a walking speed ≥1 m/s. **Note**: RSV subtype was unknown for 1 RSV-confirmed LRTD and 2 RSV-confirmed ARI episodes.

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About the AReSVi-006 trial
The AReSVi-006 (**A**dult **Re**spiratory **S**yncytial **Vi**rus) phase III trial is a randomised, placebo-controlled, observer-blind, multi-country trial to demonstrate the efficacy of a single dose of GSK's adjuvanted RSVPreF3 OA investigational vaccine in adults aged 60 years and above. Approximately 25,000 participants were enrolled from 17 countries.

This phase III efficacy trial is part of a comprehensive RSV evidence-generation programme conducted by GSK. It will continue to evaluate an annual revaccination schedule and longer-term protection over multiple seasons following one dose of the RSV vaccine candidate.

AReSVi-006 is closely monitored for safety, with safety data reviewed internally and by an external Independent Data Monitoring Committee on an ongoing basis.

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

About respiratory syncytial virus (RSV) in adults
RSV is a common contagious virus affecting the lungs and breathing passages. It is one of the major remaining infectious diseases for which there is currently no vaccine or specific treatment available for adults. Older adults are at high risk for severe disease due to age-related decline in immunity and underlying conditions. RSV can exacerbate conditions, including chronic obstructive pulmonary disease (COPD), asthma and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalisation, and death. RSV causes over 420,000 hospitalisations each year and 29,000 deaths in adults in industrialised countries. Adults with underlying conditions are more likely to seek medical advice and have higher hospitalisation rates than adults without these conditions.

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/company.

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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 in the Company's Annual Report on Form 20-F for 2021, GSK's Q2 Results for 2022 and any impacts of the COVID-19 pandemic.

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