

***Investor update:
RSV older adults and maternal
vaccine candidates***

Data presented at ID Week 2020
22 October 2020

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All expectations and targets regarding future performance and the dividend should be read together with "Assumptions related to 2020 guidance and 2016-2020 outlook" on page 68 of our second quarter 2020 earnings release.



R&D approach and RSV burden of disease

Dr Hal Barron
Chief Scientific Officer and President R&D



Vaccines R&D and RSV vaccines data

Dr. Emmanuel Hanon
Senior Vice President, Vaccines R&D



RSV opportunity

Roger Connor
President, Global Vaccines

Q&A

Presentation
25 mins

Q&A
25 mins

Science

X

Technology

X

Culture

Strengthening our R&D pipeline through a focus on science related to the immune system, the use of human genetics, and advanced technologies

Our focus on immunology is resulting in a world class Infectious Diseases portfolio



First time in human (Phase 1)

3858279* (CCL17 inhibitor) OA pain
3745417 (STING agonist) cancer
3186899* (CRK-12 inhibitor) visceral leishmaniasis
3511294* (LA anti-IL5 antagonist) asthma
3810109* (broadly neutralizing antibody) HIV
3537142* (NYESO1 ImmTAC) cancer
3439171* (H-PGDS inhibitor) DMD
3368715* (Type 1 PRMT inhibitor) cancer
3174998* (OX40 agonist) cancer
2798745* (TRPV4) DME
6097608* (CD96) cancer
C. difficile*
SAM (rabies model)
S. aureus*
COVID-19 (Clover Biopharmaceuticals)**†
COVID-19 (Medicago)**†
COVID-19 (Sanofi)**†

Proof of concept (Phase 1b/2)

3640254 (maturation inhibitor) HIV
3228836* (HBV ASO) HBV
3772847* (IL33r antagonist) asthma
Lete-cel* (3377794 NY-ESO-1 TCR) cancer
2330811 (OSM antagonist) systemic sclerosis
2330672 (linerixibat, IBATi) cholestatic pruritus in PBC
3326595* (PRMT5 inhibitor) cancer
cobolimab* (TSR-022, TIM-3 antagonist) cancer
3036656* (leucyl t-RNA inhibitor) TB
2831781* (aLAG3 depleting) ulcerative colitis
TSR-033* (LAG3 antagonist) cancer
Menveo liquid
RSV paediatric
RSV maternal*
RSV older adults**†
Therapeutic HBV**†
Malaria* (fractional dose)
Shigella*

Pivotal (Phase 2/3)

Benlysta ³ + Rituxan SLE**
cabotegravir** LA + rilpivirine* LA HIV
daprodustat (HIF-PHI) anaemia
Nucala COPD/HES/nasal polyps
belantamab mafodotin* (BCMA ADC) multiple myeloma
Zejula* (PARP inhibitor) ovarian cancer**
dostarlimab* (PD-1 antagonist) dMMR/MSI-H EC
bintrafusp alfa* (TGFβ trap/anti-PDL1) BTC**
otilimab* (3196165) RA, COVID-19⁴
gepotidacin* (2140944) uUTI and GC
3359609* (ICOS receptor agonist) HNSCC** ²
GSK4182136* SARS-CoV2 antibody
Shingrix immuno-compromised*
Bexsero infants (US)
MMR (US)
Rotarix liquid (US)
MenABCWY

Marketed

Shingrix
Bexsero
Menveo
Fluarix
Priorix / Priorix Tetra / Varilix
Infanrix / Pediarix / Boostrix
Synflorix
Hepatitis vaccines
Rotarix
Cervarix
Rukobia
Dovato
Juluca
Tivicay
Triumeq
Epzicom / Kivexa
Selzentry
Zinnat
Zeffix
Viread
Augmentin

Note: Only the most advanced indications are shown for each asset

*In-license or other alliance relationship with third party; **Additional indications also under investigation

†GSK is contributing pandemic adjuvant to COVID-19 vaccines collaborations

1. In Phase 1/2 study; 4. Otilimab in COVID-19 in Ph2a proof of concept, under investigation for inflammatory complications of coronavirus infection
TB: tuberculosis; uUTI: uncomplicated urinary tract infection; GC: gonorrhoea

RSV vaccine opportunity: high unmet need

Burden most significant in infants and older adults



About RSV

- Common respiratory virus that can be serious, especially for infants and older adults
- Most common cause of bronchiolitis and pneumonia in children <1 year of age in US¹
- Significant cause of respiratory illness in older adults
- Morbidity and mortality comparable (and more severe some seasons) to influenza
- No vaccine currently available

Disease Burden

Children under 5

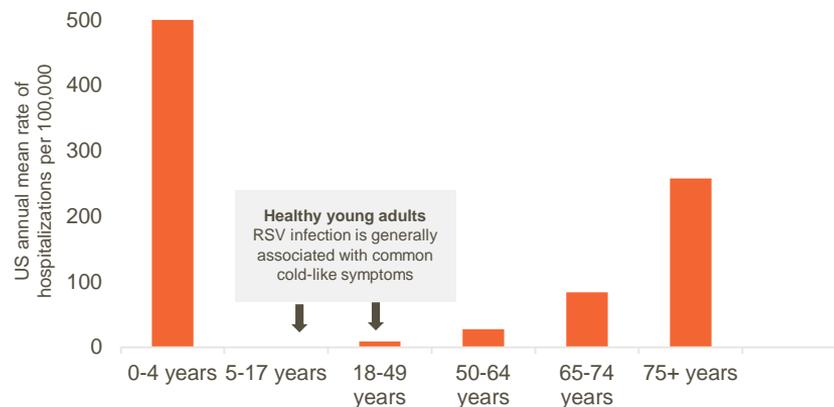
3 million hospitalisations globally per year²

Leading cause of hospitalisation in infants <1 year in the US³

Older Adults

177,000 hospitalisations, 14,000 deaths per year in the US alone⁴

RSV-associated hospitalisation burden in the USA⁵



1. <https://www.cdc.gov/rsv/about/symptoms.html>; 2. Shi T, et al. *Lancet*. 2017;390:946–58; 3. McLaurin KK, et al. *J Perinatol* 2016;36:990-6.

4. CDC - <https://www.cdc.gov/features/rsv/>; 5. 1997 – 2009 data. Figure adapted from Matias G et al. *BMC Public Health* 2017;17:271

Vaccines R&D approach

Dr. Emmanuel Hanon
Senior Vice President and Head of R&D, GSK Vaccines

Science

X

Technology

X

Culture

Design and deliver ground-breaking vaccines

- Shingrix and MenABCWY (lifecycle management)
- Key priority assets: RSV older adults, maternal, paediatric
- Therapeutic (Chronic HepB)
- Antimicrobial resistance (C. Difficile, S. Aureus)

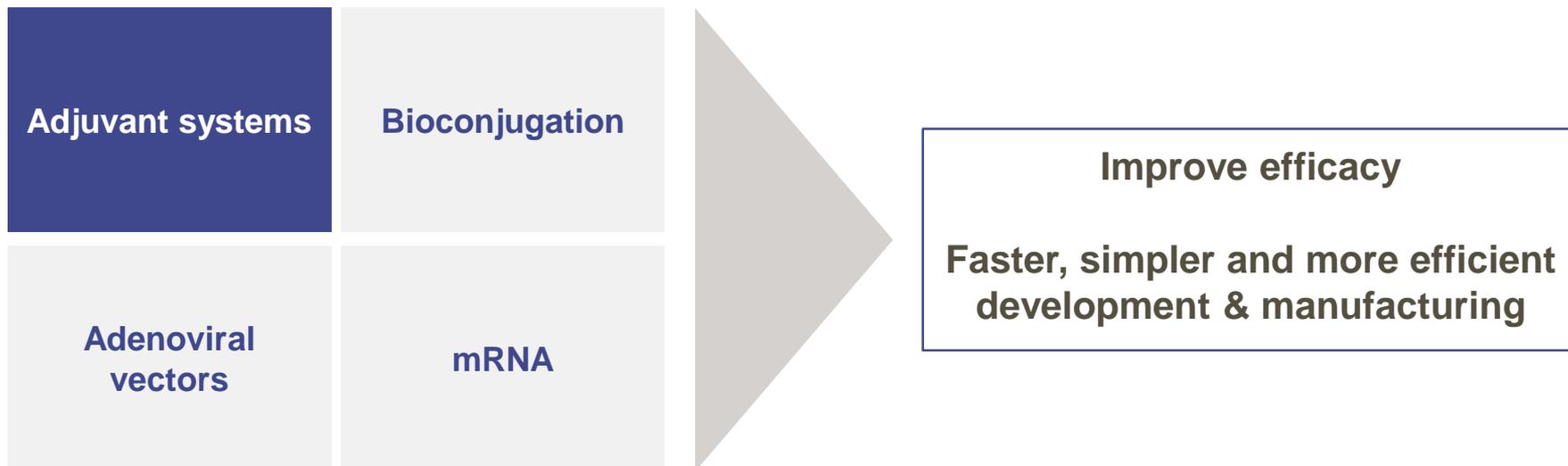
Leverage disruptive technologies

- Address unmet needs and improve vaccine efficacy
- Make manufacturing simpler and faster
- Speed up product development timelines

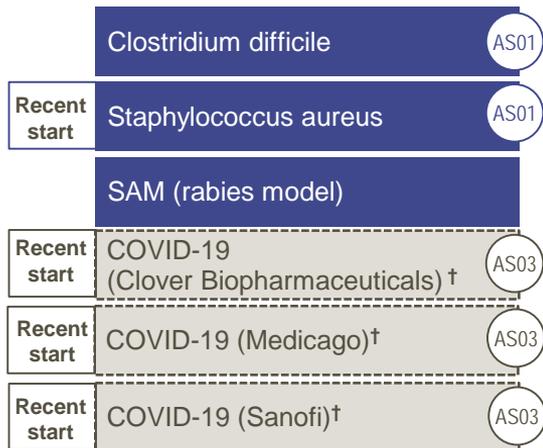
Evolve vaccines R&D

- Focus on science and resourcing to accelerate development
- Attract and retain leading scientists and best talent
- Smart risk-taking and single point of accountability

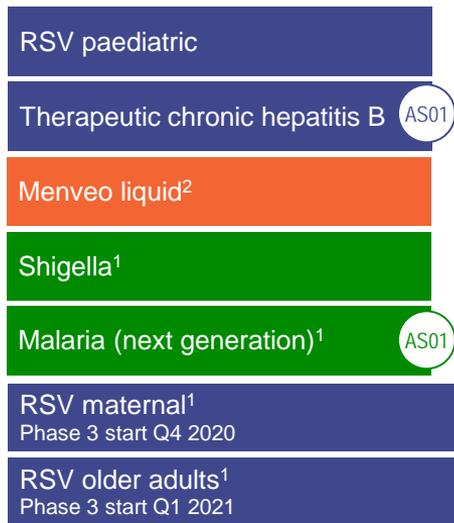
Vaccines innovation approach built on platform technologies



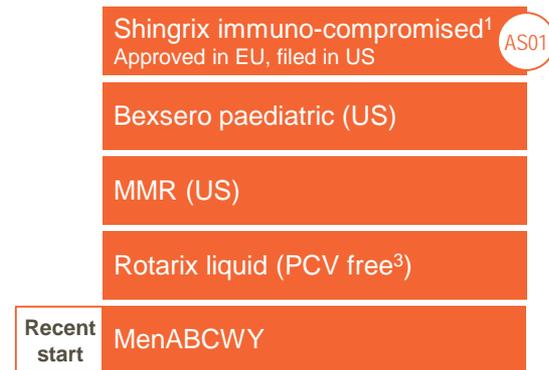
Phase 1 / 2



Phase 2



Phase 3



¹ In-license or other alliance relationship with third party

² Menveo booster also in development

³ Porcine circovirus free formulation

†GSK is contributing pandemic adjuvant to COVID-19 vaccines collaborations

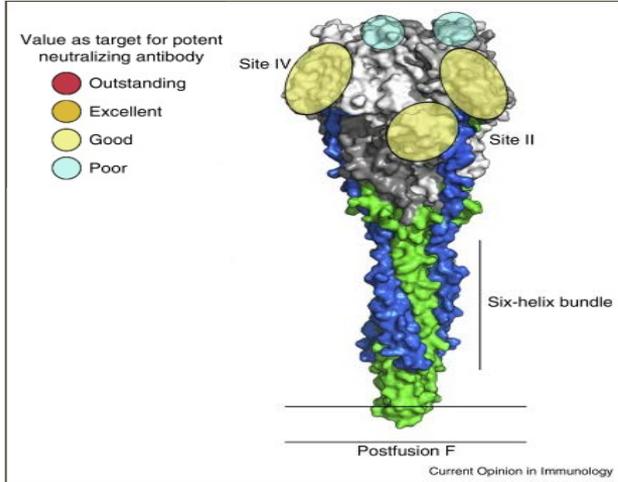
Note: Candidates using adjuvants are designated

GSK approach to RSV vaccines

Pre F protein structure gives greater chance of success

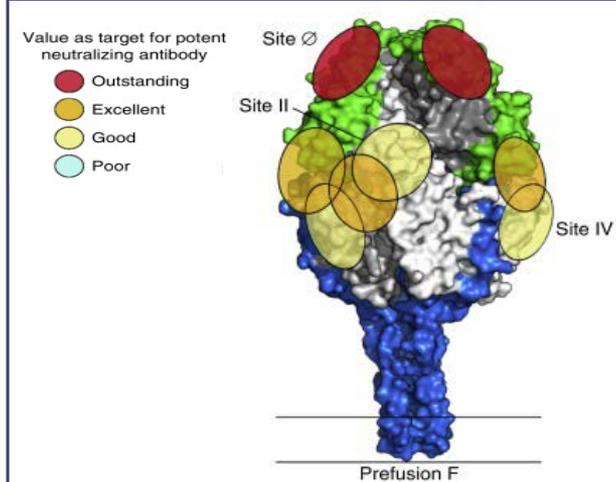


Previous approach



Limited success with post fusion RSV F protein which hides critical neutralising sites

GSK Approach



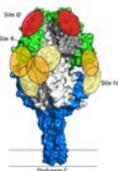
New generation pre fusion RSV F protein exposes multiple essential neutralising sites

RSV vaccine candidates

Target protection against RSV across 3 key target populations



3 RSV vaccine candidates - All with FDA fast track designation



maternal

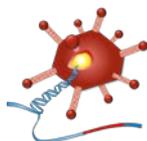
passive immunisation

Features pre-fusion antigen

Stabilised formulation designed to optimize rise in neutralising antibodies

Polyclonal maternal antibodies to confer protection for first 6 months

Phase 3 start expected Q4 2020



paediatric

active immunisation

Immunological priming to confer protection from 3 months to 2 years

Using adenoviral vector-based technology, a potent platform to induce an immunological memory

In Phase 2 development



+ older adults

AS01 active immunisation

Features pre-fusion antigen combined with AS01 adjuvant

Proven adjuvant to stimulate greater immune response in older adult population (as in Shingrix)

Phase 3 start expected Q1 2021



Key data on immunogenicity and tolerability for Maternal Vaccine Candidate (RSVPreF3) Administered to Non-pregnant Women

Data first presented at ID Week 2020
21 October 2020



Study summary

- Phase I/II, randomised, observer-blind, placebo controlled, multicentre study to evaluate the safety, reactogenicity and immunogenicity of different dose levels
- 502 healthy non-pregnant women age 18-49 years enrolled
- Received 1 intramuscular doses of either 30, 60, 120 µg of RSVPreF3 vaccine or placebo
- Solicited adverse events (AEs) for 7 days post vaccination; unsolicited AEs for 30 days post vaccination; serious adverse events (SAEs) collected for 181 days post vaccination
- Immune responses collected for 91 days post vaccination

Healthy non-pregnant women

Ages 18-45 years randomized to 4 groups (N = 500)

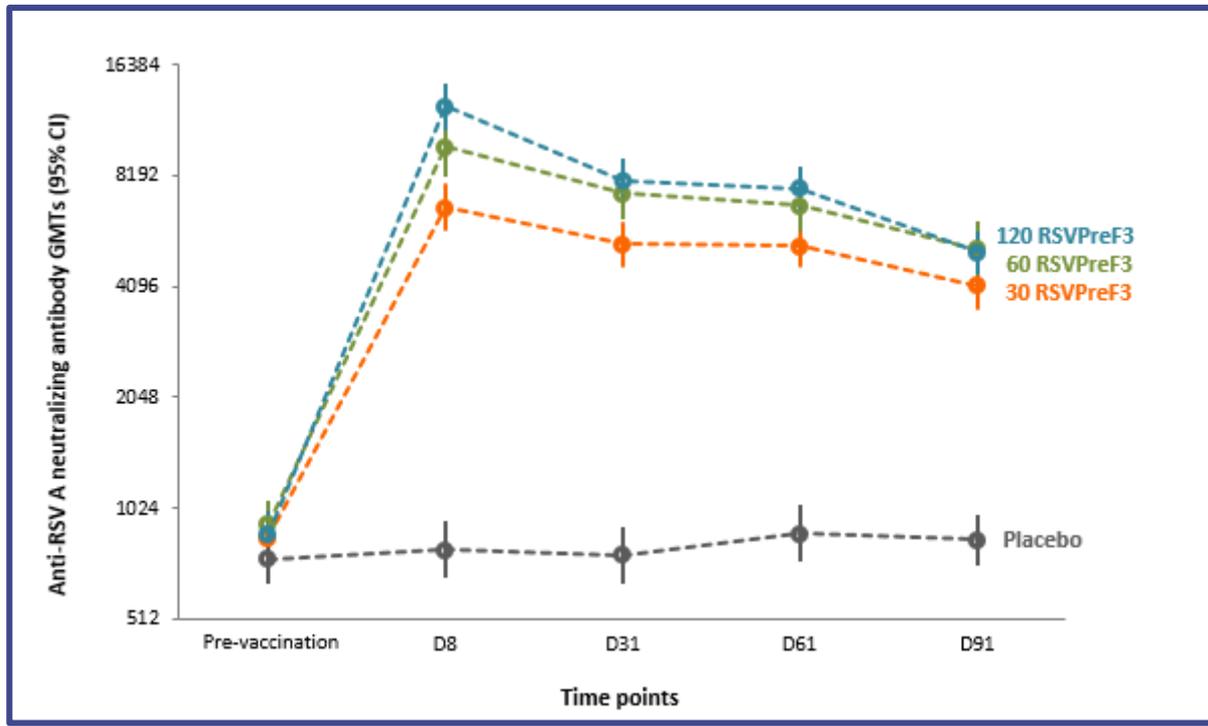
30 µg
(n = 125)

60 µg
(n = 125)

120 µg
(n = 125)

Placebo
(n = 125)

One dose is highly immunogenic and persistent at all dose levels



8-14 fold increase in RSV-A and RSV-B neutralising antibodies titers at Day 8.

Persistent immune response of 5-6 fold antibodies increase was maintained at day 91.



Safety summary

- One dose administered all dose levels was well-tolerated
- The most frequently reported solicited adverse events were pain at injection site and headache
- Low reporting of Grade 3 solicited and unsolicited AEs
- No clinically significant changes in laboratory parameters occurred
- 3 SAEs were reported; none was related to vaccination

Key data on immunogenicity and tolerability for Older Adults Vaccine Candidate

Data first presented at ID Week 2020
21 October 2020

Study designed to evaluate antigen and adjuvant vaccine doses in target population



Study summary

- Phase 1 / 2, placebo-controlled, multi-country trial
- Evaluation of low, medium, high doses of RSVPreF3 antigen with and without adjuvants
- 2 doses administered 2 months apart
- Results include antibody and T-cell immune responses up to 1 month post-dose 1
- Results of safety/reactogenicity up to 1 month post-dose 1

Part A – Young Adults

Ages 18-40 years
randomized to 4 groups
(N = 48)

30 µg
(n = 12)

60 µg
(n = 12)

120 µg
(n = 12)

Placebo
(n = 12)

Part B – Older Adults

Ages 60-80 years randomized to 10 groups (N= 1000)

30 µg
(n = 100)

30 µg AS01_E
(n = 100)

30 µg AS01_B
(n = 100)

60 µg
(n = 100)

60 µg AS01_E
(n = 100)

60 µg AS01_B
(n = 100)

120 µg
(n = 100)

120 µg AS01_E
(n = 100)

120 µg AS01_B
(n = 100)

Placebo
(n = 100)

Results in older adults showed strong induction of antibody and T-cell response



Antibody Response

Pre-specified phase 1 / 2 success criteria: **at least 6-fold increase** in RSV-A neutralising antibodies

Geometric mean of fold increase in RSV-A NAb titer 30 days post vaccination compared to pre vaccination

Dose	RSVPreF ₃ Plain	AS01 _E	AS01 _B
30 µg	5.6	5.6	6.2
60 µg	6.6	6.7	6.6
120 µg	9.9	9.5	8.0

NAb = neutralising antibody

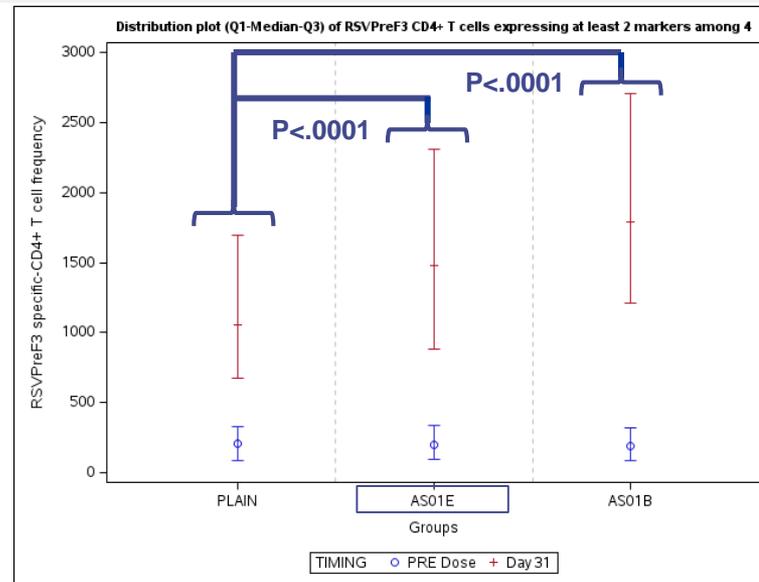
** at least 2 markers among IL-2, CD40L, TNFα, IFNγ

p-values computed by comparing the Geometric Mean Frequency (GMF) adjusted for covariates (Ancova model). (AS01_B vs Plain, AS01_E vs Plain)

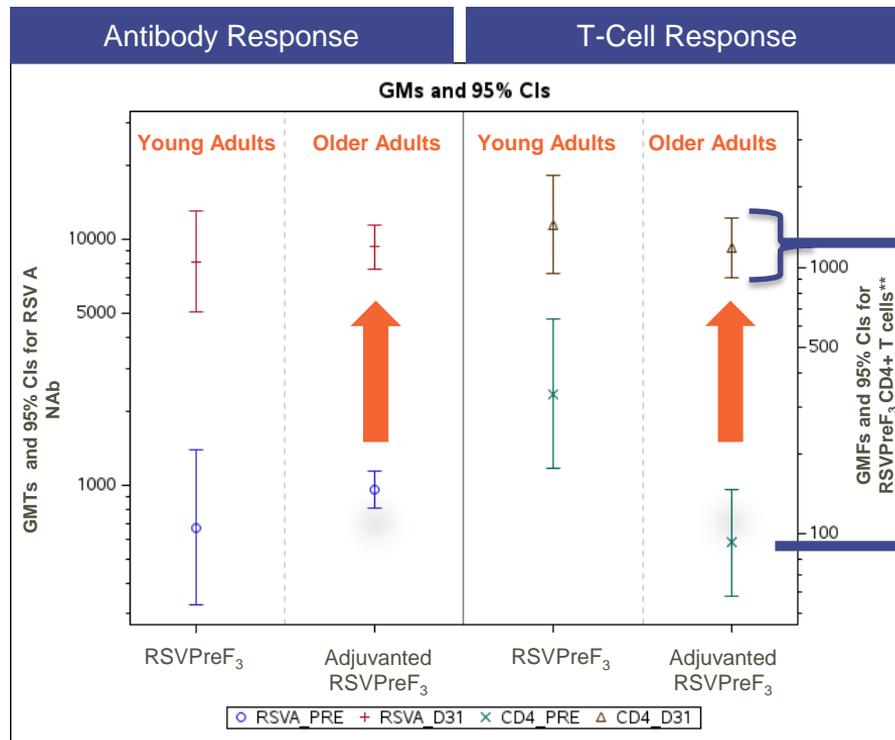
T-cell Response

Pre-specified phase 1 / 2 success criteria: **statistically demonstrated superiority of AS01 adjuvanted** over plain formulations

Increase in the frequency of RSVPreF₃ specific-CD4+ T cells expressing ≥2 markers** 30 days post vaccination compared to pre vaccination



Compelling neutralising antibody response and T-cell restoration



Meaningful boosting of neutralising antibodies response in older adults

1 month post vaccination:
Restored RSVPreF₃ CD4+ T-cell frequencies in older adults close to young adult level using adjuvanted formulations

Before vaccination:
Deficiency of RSVPreF₃ specific-CD4+ T-cells in older adults before vaccination

Results 1 month post vaccination captured D31 (day 31 post vaccination)
 GMs = geometric means; GMTs = geometric mean titers; GMFs = geometric mean frequencies; CI = confidence intervals; NAb = neutralising antibody
 ** expressing at least 2 markers among IL-2, CD40L, TNFa, IFNg

Well tolerated in older adults



Safety summary

- First dose was well tolerated
- Most frequently reported AEs were pain at injection site, fatigue and headache.
- AE rates tended to be higher after AS01_B-adjuvanted formulations compared to other vaccine formulations in OA; grade 3 AE rates were generally low
- No safety concerns for laboratory parameters nor AEs or SAEs were identified
- Low reporting of SAEs; no related or fatal SAEs
- No vaccine-related safety concerns were raised

RSV opportunity

Roger Connor
President, GSK Vaccines

RSV older adults represents major opportunity



Significant, widespread health burden

- ~70m¹ age 60+ (target US population)
- Infection can lead to pneumonia
- No specific treatment or prevention for RSV infection in older adults²

US disease burden (per year)

- 177,000 hospitalisations²
- 14,000 deaths²

Vaccination offers likely best solution

- Older adults are at greater risk than young adults for serious complications from RSV because immune systems weaken with age²
- Symptoms, burden and seasonality similar to influenza
- Opportunity to improve health outcomes and reduce healthcare costs

First-in-class potential

- Data supports adjuvanted approach for boosting neutralizing antibodies response and achieving T-cell restoration
- Phase 3 programme on track to commence Q1 2021

1. US Census: <https://www.census.gov/data/tables/2018/demo/age-and-sex/2018-older-population.html>

2. CDC - <https://www.cdc.gov/rsv/high-risk/older-adults.html>

Maternal vaccination offers potential for broad protection from birth to 6 months



Burden most significant in young infants

- ~4m annual birth cohort in the US¹
- Leading cause of hospitalisation in infants <1 year in the US²
- Nearly half of paediatric hospitalizations and deaths occur in infants <6 months of age³

Opportunity to protect infants from birth

- Protect infants from birth up to 6 months of life through transfer of maternal antibodies
- Potential to protect mothers and reduce transmission from mother to child
- Possible co-administration with other recommended vaccines for pregnant women (pertussis and/or flu)
- Induction of polyclonal antibody response could help reduce the risk of escape mutant viruses
- Phase 3 start on track for Q4 2020
- Data in pregnant women to be presented in 2021

Integrated maternal and paediatric programmes target protection where burden most significant

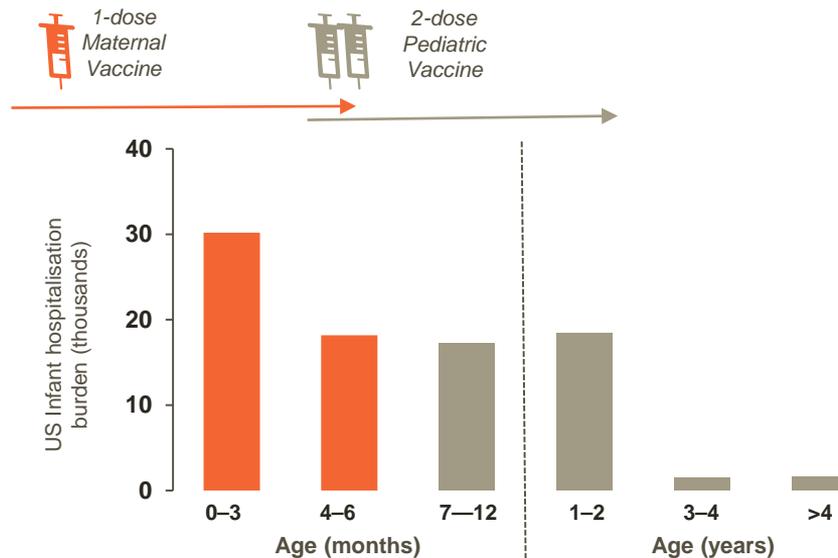


Figure adapted from PharmacoEconomics, Economic Impact of Respiratory Syncytial Virus-Related Illness in the US, Vol. 22, 2004, 275-284. Paramore LC et al. © Adis Data Information BV with permission of Springer; RSV, respiratory syncytial virus

Our RSV assets offer a compelling opportunity for GSK



Opportunity is significant



Older adults

- Potential first-in-class with differentiated adjuvant
- 70m adults age 60+ in the US¹; >300m in developed regions²
- ~2/3 of older adults in US receive flu or pneumococcal vaccines²



Pregnant women

- Protect infants from birth up to 6 months of life
- Potential to expand portfolio of other recommended vaccines for pregnant women
- 4m birth cohort in US³; globally >130m⁴
- ~50% of pregnant women in US receive flu and/or pertussis vaccines⁵

Data support move to pivotal studies

- Compelling neutralising antibodies response and T-cell restoration in older adults; well tolerated
- Phase 3 start on track for Q1 2021; initial data expected in H2 2022*
- Immunogenic response; good safety profile
- Data in pregnant women in-house and supportive of advancement
- Maternal phase 3 to start Q4 2020; initial data expected in H2 2022*

1. US Census: <https://www.census.gov/data/tables/2018/demo/age-and-sex/2018-older-population.html>;
2. CDC: <https://www.cdc.gov/nchs/products/databriefs/db281.htm>; 3. CDC: <https://www.cdc.gov/nchs/nvss/births.htm>;
4. United Nations World Population Prospects 2019, 5. CDC: <https://www.cdc.gov/vitalsigns/maternal-vaccines/index.html>

*Timing dependent on RSV infection circulation during pandemic lockdowns.

Q&A