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For media and investors only

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GSK and Zhifei revise and extend strategic vaccine collaboration in China

- *Shingrix* collaboration extended to 2034
- Expanded exclusive rights to explore collaboration with Zhifei on *Arexvy*
- Creates sustainable, long-term collaboration to bring innovative vaccines to more than 500 million people in China

GSK plc (LSE/NYSE: GSK) today announced that it has entered into an agreement with Chongqing Zhifei Biological Products, Ltd. (Zhifei) to revise the terms on which Zhifei will commercialise GSK's shingles vaccine, *Shingrix*, in mainland China. The revised agreement extends the original 3-year period (2024-2026) during which Zhifei has exclusive rights to import, distribute and co-promote the vaccine in mainland China for an additional 8 years through to 2034, with revised expected volumes. Under the revised agreement, Zhifei also agrees to engage exclusively with GSK to explore a potential collaboration, with an initial term of 10 years, on the commercialisation of a respiratory syncytial virus (RSV) vaccine in mainland China, subject to regulatory approval of the vaccine.

Zhifei is the largest Chinese vaccine company by revenue, has an extensive network which covers more than 30,000 vaccination points across the country, and a strong track record of driving access to innovative vaccines in China.

Luke Miels, Chief Commercial Officer, GSK, said: "This revised agreement with Zhifei puts our collaboration on a sustainable footing, managing challenges in the macro environment in the near-term, and helping us to reach even more Chinese people with our innovative adult vaccines over the long-term."

Financial Considerations

This agreement amends the agreement previously announced in October 2023. Subject to the terms of the revised agreement, the parties expect Zhifei will purchase volumes of *Shingrix*, phased over time, with a potential total value to GSK of £2.3bn (at current exchange rates) over the 6-year period 2024-2029. Previously contracted minimum purchase levels no longer apply.

About shingles

Shingles, also known as herpes zoster, is caused by a reactivation of the varicella-zoster virus (VZV) – the same virus that causes chickenpox¹. Globally, most people aged 50 and over have the dormant VZV in their nervous system and are at risk of developing shingles^{2,3}. As people age, the immune system's strength wanes, leading to a decreased response to infection and thus increasing the risk of developing shingles^{1, 2, 3, 4, 5}. People with a suppressed or compromised immune system are also at risk of shingles⁶.

Shingles typically presents as a rash with painful chest, abdomen, or face blisters¹. The pain is often described as aching, burning, stabbing or shock-like⁵. Following a rash, a person can also experience post-herpetic neuralgia (PHN), a long-lasting nerve pain that can continue for weeks or months and sometimes persist for several years⁵. PHN is the most common complication of shingles, occurring in 5-30% of all cases, depending on the individual's age⁷.



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Following expedited review, *Shingrix* was approved by China's National Medical Products Administration (NMPA) to prevent shingles in adults aged 50 years or older in May 2019. Estimates suggest that by 2030, there will be 570 million people over the age of 50 in China, yet as at June 2023, only around 1.2% of the urban population of those between 50-74 years old had been vaccinated against shingles.

About *Shingrix*

Shingrix (Recombinant Zoster Vaccine or RZV) is a non-live, recombinant subunit vaccine indicated for the prevention of shingles in adults aged 50 and over. It combines an antigen, glycoprotein E, with an adjuvant system, AS01e, and may help overcome the natural age-related decline in responses to immunisation that contributes to the challenge of protecting adults ages 50 and over from shingles^{8,9}. RZV is not indicated to prevent primary varicella infection (chickenpox). In some countries, RZV is also approved for adults aged 18 or over at increased risk for shingles. The use of the vaccine should be in accordance with official recommendations.

About RSV

RSV is a common contagious virus affecting the lungs and breathing passages. Adults can be at increased risk for RSV disease due to comorbidities, immune compromised status, or advanced age. RSV can exacerbate conditions, including COPD, asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalisation, and death.¹⁰ In older adults, RSV is associated with similar rates of complications and severe outcomes as influenza¹¹. There are approximately 297 million people aged 60+ in China¹² and it is estimated that over ¾ of them suffer from at least one chronic disease. That shows the potential significant disease burden of RSV in 60+ Chinese population.

About GSK's RSV Vaccine

Respiratory Syncytial Virus Vaccine (recombinant), contains recombinant RSV glycoprotein F stabilised in the prefusion conformation (RSVPreF3). This antigen is combined with GSK's proprietary AS01E adjuvant.

In May 2023, the US FDA approved GSK's RSV vaccine for the prevention of lower respiratory tract disease (LRTD) caused by RSV (RSV-LRTD) in individuals 60 years of age and older. In June 2024, the FDA also approved the vaccine for individuals 50-59 who are at increased risk for RSV-LRTD. The vaccine has also been approved for the prevention of RSV-LRTD in individuals 60 years of age and older in over 40 countries. Regulatory reviews for both the use of the vaccine in individuals 60 years of age and older and those aged 50-59 at increased risk are ongoing in multiple countries. The proposed trade name remains subject to regulatory approval in other markets.

GSK has global clinical development programmes underway to evaluate the safety and immunogenicity of Arexvy in adults aged 18+ at increased risk of RSV disease.

The GSK proprietary AS01 adjuvant system contains STIMULON QS-21 adjuvant licensed from Antigenics LLC (formerly Antigenics Inc.), a wholly owned subsidiary of Agenus Inc. STIMULON is a trademark of SaponiQx Inc., a subsidiary of Agenus.

The use of this vaccine should be in accordance with official recommendations. As with any vaccine, a protective immune response may not be elicited in all vaccinees.

The vaccine is not approved in China at this time.



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About Zhifei

Chongqing Zhifei Biological Products Co., Ltd. is a fully integrated biotechnology company that specialises in vaccine and biopharmaceutical research, development, production, sales, promotion, distribution, and import/export. Zhifei is committed to the mission of “preventing diseases and safeguarding human health”.

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 Q3 Results for 2024.

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- 8 Cunningham et al. Vaccine profile of herpes zoster (HZ/su) subunit vaccine. *Expert Review of Vaccines*. 2017;16:7;661-670.
- 9 The GSK proprietary AS01 adjuvant system contains QS-21 Stimulon® adjuvant licensed from Antigenics LLC, a wholly owned subsidiary of Agenus Inc. (NASDAQ: AGEN), MPL and liposomes.
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