



GSK's RSV vaccine candidate for older adults, containing Agenus' QS-21 STIMULON™ as part of GSK's AS01 adjuvant, reports positive pivotal data supporting initiation of global regulatory submissions

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- First RSV vaccine candidate to show statistically significant and clinically meaningful efficacy in adults aged 60 years and above
- Third AS01 adjuvanted vaccine containing QS-21 STIMULON to deliver meaningful clinical benefit against infections in a registrational program
- Global regulatory submissions are anticipated to begin in the second half of 2022

LEXINGTON, Mass., June 10, 2022 (GLOBE NEWSWIRE) -- Agenus (NASDAQ: AGEN), an immuno-oncology company with an extensive pipeline of therapies and adjuvants designed to activate the immune response to cancer and infections, today shared that partner GSK announced positive headline results from a pre-specified efficacy interim analysis of the AReSVi 006 phase III trial evaluating their investigational RSV vaccine in adults aged 60 years and above. The primary endpoint was exceeded with no unexpected safety concerns observed. Engagement with regulators is planned to start immediately with anticipated regulatory submissions in H2 2022.

"The need for vaccines offering long-lasting efficacy and scalable production processes has been amplified by the current pandemic. The effectiveness and durability of vaccines containing QS-21 STIMULON has been demonstrated in *Shingrix*, with best-in-class protection exceeding 9 years. Our subsidiary, SaponiQx, is developing a proprietary plant cell culture manufacturing process designed to enable broader use of QS-21 STIMULON through a sustainable, eco-friendly production method scalable to address pandemic and other vaccine needs," said Dr. Garo H. Armen, Chief Executive Officer of Agenus Inc.

GSK's RSV vaccine candidate contains Agenus' proprietary QS-21 STIMULON within its AS01 adjuvant, which – in the context of other antigens – has already demonstrated positive immune responses as well as a favorable safety profile. QS-21 STIMULON is a critical component of the AS01 adjuvant used in multiple GSK vaccines, including GSK's FDA approved *Shingrix* shingles vaccine, and the world's first malaria vaccine *Mosquirix*, endorsed by the WHO.^{1,2}

Agenus' subsidiary, SaponiQx, has developed a plant cell culture method of manufacturing QS-21 STIMULON, which is designed to support its broader use based on sustainable, scalable, and cost-effective supply. SaponiQx expects to generate GMP material using this process before the end of the year to enable partner clinical trials. Once SaponiQx's plant cell culture process is fully scaled, Agenus' wholly-owned manufacturing campus is designed to support the capacity for broad use across disease settings, as well as scalability to address future pandemic threats.

About Agenus

Agenus is a clinical-stage immuno-oncology company focused on the discovery and development of therapies that engage the body's immune system to fight cancer and infections. The Company's vision is to expand the patient populations benefiting from cancer immunotherapy by pursuing combination approaches that leverage a broad repertoire of antibody therapeutics, adoptive cell therapies (through its subsidiary MiNK Therapeutics), and adjuvants (through its subsidiary SaponiQx). The Company is equipped with a suite of antibody discovery platforms and a state-of-the-art GMP manufacturing facility with the capacity to support clinical programs. Agenus is headquartered in Lexington, MA. For more information, please visit www.agenusbio.com and our Twitter handle @agenus_bio. Information that may be important to investors will be routinely posted on our website and Twitter.

Statement Regarding Forward-Looking Statements

*This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding QS-21 STIMULON adjuvant, alone and formulated in vaccines and vaccine candidates such as GSK's RSV vaccine candidate, *Shingrix* and *Mosquirix*, for instance, statements regarding vaccine efficacy, safety, mechanism of action and durability; clinical development and regulatory plans and timelines; current and future manufacturing capabilities, including our ability to scale-up manufacturing and to manufacture in a consistent, sustainable, eco-friendly, and cost effective manner; the ability of QS-21 STIMULON adjuvant to be used in effective and safe vaccines for the prevention and/or treatment of Covid-19 and other infectious disease; anticipated corporate milestones, including our ability to partner, license and/or otherwise monetize the QS-21 STIMULON adjuvant; and any other statements containing the words "may," "believes," "expects," "is designed to," "estimates," "will," "establish," "validated," "best in class," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, among others, the factors described under the Risk Factors section of our most recent Quarterly Report on Form 10-Q or Annual Report on Form 10-K filed with the Securities and Exchange Commission. Agenus cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and Agenus undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.*

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¹ *Shingrix* and *Mosquirix* trade marks are owned by or licensed to the GSK group of companies. QS-21 STIMULON trade mark is owned by Agenus, Inc.

² <https://www.who.int/news/item/06-10-2021-who-recommends-groundbreaking-malaria-vaccine-for-children-at-risk>