GSK's Shingrix Containing Agenus' QS-21 Stimulon® Adjuvant Receives Marketing Authorization from Health Canada

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First approval for a vaccine enhanced with QS-21 Stimulon®

LEXINGTON, Mass., Oct. 13, 2017 /PRNewswire/ -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with a pipeline of immune checkpoint antibodies and cancer vaccines, announced today that Health Canada granted marketing authorization to GlaxoSmithKline's (GSK) shingles vaccine, Shingrix, that contains Agenus' proprietary immune adjuvant QS-21 Stimulon® adjuvant. The approval in Canada marks the first approval for Shingrix and the first approval of a vaccine containing QS-21 Stimulon.

In September of this year, Shingrix, was unanimously recommended for approval by the FDA Vaccines and Related Biological Products Advisory Committee. A decision by FDA on whether to approve Shingrix in the United States is anticipated in the coming weeks.

QS-21 Stimulon is an immune-potent adjuvant designed to help the body generate antibodies and T cells, which guard against infection with viruses, parasites and bacteria. The approval of Shingrix in Canada is based on efficacy data collected in more than 37,000 people which demonstrated an efficacy rate against shingles greater than 90%,and this is independent from age (≥50 and ≥70 years of age), as well as a sustained efficacy over the entire follow-up period. Most common side effects reported in clinical trials were pain, redness and swelling at the injection site and the majority of which were transient and mild to moderate in intensity, lasting less than three days.

"The approval of the Shingrix vaccine containing Agenus' QS-21 Stimulon is a major and most exciting development for the eligible population for GSK, and for Agenus. This approval confirms our belief that the addition of our proprietary immune adjuvant improves vaccine effectiveness and, ultimately, brings benefit to patients," said Garo Armen, Ph.D., Chairman and CEO, Agenus. "The Canadian approval marks the first of further decisions on approvals for Shingrix. We look forward to the FDA decision in the near future."

The addition of QS-21 Stimulon is being studied to determine its potential to help a diverse range of vaccines work more effectively to treat or cure difficult-to-treat diseases, like cancer. QS-21 Stimulon is currently being used in combination with Agenus' neoantigen vaccine, AutoSynVax™, now in a Phase 1 clinical trial in cancer.

QS-21 Stimulon is also currently being evaluated in numerous GSK vaccine development candidates for both therapeutic and prophylactic applications.

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. The Company's vision is to expand the patient populations benefiting from cancer immunotherapy by pursuing a number of combination approaches that leverage a broad repertoire of antibody therapeutics and proprietary cancer vaccine platforms. 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 early phase clinical programs. Agenus is headquartered in Lexington, MA. For more information, please visit www.agenusbio.com; information that may be important to investors will be routinely posted on our website.

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 the FDA's pending review of GSK's BLA for Shingrix and further regulatory decisions on approvals for Shingrix, as well as statements regarding Agenus' product candidates and clinical trial plans and activities, including the potential for QS-21 Stimulon to help a diverse range of neoantigen vaccines work more effectively to potentially cure difficult-to-treat diseases like cancer. 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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