FDA Approves GSK's Shingles Vaccine with Agenus' QS-21 Stimulon® Adjuvant

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- SHINGRIX containing QS-21 Stimulon® demonstrates remarkable efficacy of greater than 90% in pooled studies against shingles

- Shingles is a major public health issue in the US, impacting as many as 1 in 3 adults over the age of 50 years

LEXINGTON, Mass., Oct. 20, 2017 /PRNewswire/ -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with a pipeline of immune checkpoint antibodies and cancer vaccines, announced today that the US Food and Drug Administration (FDA) granted marketing authorization to GlaxoSmithKline's (GSK) herpes zoster vaccine, SHINGRIX, containing Agenus' proprietary immune adjuvant QS-21 Stimulon®. SHINGRIX is indicated for prevention of herpes zoster (also known as shingles) in adults aged 50 years and older. The addition of QS-21 Stimulon helps improve the vaccine's effectiveness by boosting immune response in older adults who often experience age-related decline in immunity.

Shingles is a major public health issue in the US, impacting as many as 1 in 3 older adults over the age of 50 years. Shingles is caused by a virus called varicella zoster, which is also known as the chicken pox virus. Nearly all older adults have the varicella zoster virus dormant in their nervous system waiting to reactivate with advancing age and weakened immune systems.

QS-21 Stimulon is an immune-potent adjuvant designed to boost the immune system by helping the body generate antibodies and T cells that guard against infection. The addition of QS-21 Stimulon to the SHINGRIX vaccine enhances the immune response in these older adults.

"We are delighted by the remarkable efficacy of SHINGRIX, containing our proprietary QS-21 Stimulon adjuvant and the public health benefit; this FDA approval marks a significant milestone for Agenus," said Garo Armen, Ph.D., Chairman and CEO, Agenus. "The addition of QS-21 Stimulon enhances the immunogenicity of SHINGRIX and is beneficial in an older adult population who often experience a decline in immunity. Beyond shingles, our QS-21 Stimulon is under investigation in numerous vaccines and is a critical component of our neoantigen vaccine formulation, which is currently advancing in a Phase 1 clinical trial in patients with cancer."

The FDA approval of SHINGRIX was based on data pooled from two pivotal Phase III clinical trials in more than 37,000 people, which demonstrated an efficacy rate against shingles greater than 90% independent of age, as well as a sustained efficacy over the four-year follow-up period. SHINGRIX also reduced the overall incidence of postherpetic neuralgia (PHN), the most common and oftentimes debilitating chronic nerve pain associated with shingles. The benefit of SHINGRIX in the prevention of PHN can be attributed to the effect of the vaccine on the prevention of shingles. The most common side effects reported in clinical trials of SHINGRIX were pain, redness and swelling at the injection site, the majority of which were transient and mild to moderate in intensity, lasting less than three days.

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 GSK's 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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