Annexon Biosciences Announces FDA Fast Track Designation for Novel C1q Inhibitor ANX005 for the Treatment of Guillain-Barré Syndrome

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– Annexon plans to advance the clinical development of ANX005 for the treatment of GBS –

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Annexon Biosciences, a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the body, eye and brain, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ANX005 for the treatment of Guillain-Barré Syndrome (GBS), a rare, acute, antibody-mediated autoimmune disease impacting the peripheral nervous system for which there are currently no approved therapies in the United States. The FDA had previously granted Orphan Drug designation for ANX005 for the treatment of GBS.

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“Fast Track designation is a testament to the urgent need for a new therapy to treat patients with GBS, as there are no FDA-approved therapies for this debilitating neurological disease,” said Doug Love, Esq., Annexon’s president and chief executive officer. “Having completed our Phase 1b clinical trial in patients with GBS, we look forward to advancing ANX005 into later- stage clinical trials. Our goal is to bring ANX005 to patients with GBS as quickly as possible.”

Fast Track is a designation granted by the FDA to expedite the development, review and potential approval of investigational product candidates that are intended to treat serious or life-threatening diseases or conditions with an unmet medical need. A product candidate granted Fast Track Designation may be eligible for several benefits, including more frequent meetings and communications with the FDA and, if relevant criteria are met, the potential for Accelerated Approval, Priority Review or Rolling Review of a New Drug Application (NDA) or Biologics License Application (BLA). Orphan Drug is a designation granted by the FDA for novel product candidates that are intended to treat rare diseases or conditions.

About ANX005
ANX005 is a clinical-stage investigational monoclonal antibody intended to treat patients suffering from autoimmune and neurodegenerative disorders. This novel therapy is formulated for intravenous administration and is designed to inhibit C1q and the entire classical complement pathway. Annexon has completed a Phase 1b clinical trial of ANX005 and plans to advance ANX005 into later-stage clinical trials in Guillain-Barré Syndrome (GBS). ANX005 has received both Fast Track and Orphan Drug designations from the U.S. Food and Drug Administration for the treatment of GBS. Beyond GBS, Annexon plans to develop ANX005 for additional autoimmune and neurodegenerative diseases.

About Guillain-Barré Syndrome
Guillain-Barré syndrome (GBS) is a rare, acute autoimmune disease in which the body’s immune system mistakenly attacks part of its peripheral nervous system. GBS is typically triggered by a preceding infection and usually involves rapidly progressive weakness in the limbs that may culminate within four weeks to widespread peripheral nerve damage and paralysis. In 2011, GBS was estimated to affect 0.8 to 1.9 per 100,000 persons in North America and Europe annually. There is no known cure for GBS, and there are no approved therapies for GBS in the United States. Despite the utilization of plasmapheresis (also known as plasma exchange) and high-dose immunoglobulin therapy (IVIg), many patients are left with residual neurological disability, accompanied by chronic pain and fatigue.

About Annexon Biosciences
Annexon is a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the body, eye and brain. The Company’s pipeline is based on its platform technology addressing well-researched classical complement-mediated autoimmune and neurodegenerative disease processes, both of which are triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. The Company’s first product candidate, ANX005, is a full-length monoclonal antibody formulated for intravenous administration in autoimmune and neurodegenerative disorders. The Company’s second product candidate, ANX007, is a monoclonal antibody antigen-binding fragment (Fab) formulated for intravitreal administration for the treatment of neurodegenerative ophthalmic disorders. Based on learnings from its initial trials, Annexon is advancing its current programs while evaluating additional orphan and large market indications. Annexon is deploying a disciplined, biomarker-driven development strategy designed to establish that each of its product candidates is engaging the specific target at a well-tolerated therapeutic dose in the intended patient tissue. For more information, visit www.annexonbio.com.

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