NEWS RELEASE

NS Pharma

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FDA Grants Fast Track Designation to NS-229 for the Treatment of Eosinophilic Granulomatosis with Polyangiitis

PARAMUS, NJ: September 9, 2025 – NS Pharma, Inc. (NS Pharma) a subsidiary of Nippon Shinyaku Co., Ltd. (Nippon Shinyaku), announced today that the U.S Food & Drug Administration (FDA) has granted Fast Track designation to NS-229, which is being developed for the treatment of the rare disease eosinophilic granulomatosis with polyangiitis (EGPA). NS-229 is being investigated as a selective Janus kinase 1 (JAK1) inhibitor to help regulate immune cell function and prevent the immune system from causing tissue damage.

FDA Fast Track designation status is granted to treatments of serious medical conditions that fulfil an unmet medical need. This designation allows for expedited FDA review, including more frequent collaboration with the FDA throughout the application process, to facilitate the delivery of important new therapies more quickly. NS-229 was granted Orphan Drug Designation by the FDA in April 2025.

About EGPA

EGPA, previously known as Churg-Strauss syndrome, is a rare autoimmune disease that causes inflammation in the small-to-medium-sized blood vessels which can cause tissue and organ damage to the lungs, sinuses, peripheral nerves, skin, and kidneys. EGPA is generally preceded by symptoms of bronchial asthma and allergic rhinitis. The cause is unknown. It is estimated that EGPA affects between 5,600 and 14,500 people in the U.S.*

A Phase 2, double-blind, randomized placebo-controlled global study of NS-229 is being conducted by Nippon Shinyaku and NS Pharma to assess the efficacy and safety of the investigational JAK1 inhibitor NS-229, in treating EGPA patients. By inhibiting JAK1, NS-229 may help regulate the overactive immune response characteristic of EGPA, potentially limiting the damage to heathy tissues.

About NS Pharma, Inc.

NS Pharma, Inc., is a wholly owned subsidiary of Nippon Shinyaku Co., Ltd. NS Pharma is a registered trademark of the Nippon Shinyaku Co., Ltd. For more information, please visit nspharma.com.

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**Estimated prevalences 1.7 / 100,000[1)] and 4.4 / 100,000[2)] were multiplied by a 2023 U.S. population estimate of around 330 million and rounded to nearest hundred.*

1) Bell, CF., Lau, M., Shen, Q. Clinical and Economic Characteristics of Patients Diagnosed with Eosinophilic Granulomatosis with Polyangiitis (EGPA, formerly Churg-Strauss Syndrome) in the United States [abstract]. Arthritis Rheumatol. 2018; 70 (suppl 9).

2) Berti A, Cornec D, Crowson CS, Specks U, Matteson EL. The Epidemiology of Antineutrophil Cytoplasmic Autoantibody-Associated Vasculitis in Olmsted County, Minnesota: A Twenty-Year US Population-Based Study. Arthritis Rheumatol. 2017;69:2338-2350.