NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

September 9, 2025

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

Kyoto, Japan, September 9, 2025 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to NS-229 which is being developed for the treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA).

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 has already been granted Orphan Drug Designation by the FDA and the European Commission.

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.

NS-229 is a selective JAK1 inhibitor developed in-house. NS-229 is expected to suppress excessive activation of immune cells such as T cells, B cells, and eosinophils, leading to potential reduction of tissue damages, and is expected to suppress various symptoms of EGPA.

A global Phase II study of NS-229 is being conducted in North America, Europe and Japan by Nippon Shinyaku and its U.S. subsidiary NS Pharma, Inc (Headquarters: New Jersey, USA, President: Yukiteru Sugiyama) .

Nippon Shinyaku is committed to develop potential medicines for the treatment of intractable and rare diseases, aiming to offer a useful therapy to improve the quality of life for people with EGPA.

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