NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

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The European Commission Grants Orphan Drug Designation to NS-229 for the Treatment of Eosinophilic Granulomatosis with Polyangiitis

Kyoto, Japan, January 22, 2024 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced that the European Commission (EC) has granted Orphan Drug Designation to NS-229 which is being developed for the treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA).

The Orphan Drug Designation by the EC is issued to drugs which are intended for diseases that affect fewer than five in 10,000 people in the European Union and are life-threatening or chronically debilitating. The Orphan Drug Designation provides NS-229 with potential ten years of exclusive marketing rights.

EGPA is an intractable and rare autoimmune disease of unknown etiology. EGPA is generally preceded by symptoms of bronchial asthma and allergic rhinitis. Subsequently, eosinophilic inflammation, granulomatous lesions, and necrotizing vasculitis onset along with marked eosinophilia. These symptoms are caused in various organs such as lungs, sinuses, peripheral nerves, skin, and kidney. NS-229 is a JAK1 selective inhibitor developed in-house, and suppresses excessive activation of T cells, B cells and eosinophils. As a result, it is expected to reduce tissue damage and suppress various symptoms of EGPA.

A Phase II global study of NS-229 is scheduled to be conducted by our overseas subsidiary NS Pharma, Inc. (Headquarters: New Jersey, USA, President: Tsugio Tanaka). In Japan, we are also preparing the study.

Nippon Shinyaku has been working actively having a sense of mission to develop agents for the treatment of intractable and rare diseases, with a view to launching products for EGPA patients as soon as possible.

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