NEWS RELEASE

NS Pharma

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

PARAMUS, NJ: January 22, 2024 – NS Pharma, Inc. (NS Pharma), a subsidiary of Nippon Shinyaku Co., Ltd, announced today that the European Commission (EC) has granted orphan drug designation to NS-229, which is being developed for the treatment of the rare disease eosinophilic granulomatosis with polyangiitis (EGPA).

The orphan drug designation by the EC is issued for drugs which are intended to treat 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 Pharma with a ten-year marketing exclusivity period, supporting the company's continued development and evaluation of this therapy.

EGPA is an autoimmune disease that is generally preceded by symptoms of bronchial asthma and allergic rhinitis. This inflammation in the small blood vessels can cause tissue and organ damage to the lungs, sinuses, peripheral nerves, skin, and kidneys. The cause of EGPA is unknown.

"EGPA is a serious, life-threatening disease with unmet medical need," explained NS Pharma Vice President, Research & Development, Takeshi Seita. "We are encouraged that our innovative therapy will proceed in development for the patients who need treatment."

NS-229 is a potent and selective Janus kinase (JAK) 1 inhibitor, developed in-house, which suppresses excessive activation of T cells, B cells and certain white blood cells. As a result, it is anticipated that NS-229 could reduce tissue damage and curb various symptoms of EGPA. A Phase II global study of NS-229 is scheduled to be conducted by NS Pharma.

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 group of companies. For more information, please visit nspharma.com.

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