PRESS RELEASE

NERVIANO MEDICAL SCIENCES

PART OF NMS GROUP

Nerviano Medical Sciences received European Medicines Agency (EMA) Orphan Drug Designation for its next-generation FLT3 inhibitor NMS-03592088 for treatment of Acute Myeloid Leukemia

NERVIANO, IT and BOSTON, Mass, 4 March, 2024 - Nerviano Medical Sciences S.r.l. (NMS), a part of NMS Group S.p.A. (NMS Group) and Nerviano Medical Sciences, Inc. (NMS-US), a wholly owned subsidiary of NMS Group, focused on the discovery and development of oncology drugs and the largest oncological R&D company in Italy, announced that European Commission has granted Orphan Drug Designation (ODD) for NMS-03592088 for the treatment of Acute Myeloid Leukemia (AML), just a few weeks after the US Food and Drug Administration (FDA) approval.

NMS-0359288 is a next generation FLT3 inhibitor with superior activity and selectivity with respect to approved FLT3 inhibitor drugs and higher potency on the resistance mutation F691L opening opportunities for treatment of patients who failed prior FLT3 inhibitor treatment. NMS-03592088 is being evaluated as monotherapy in a Phase I/II study in relapsed/refractory FLT3 positive AML in Europe and US. Preliminary evidence of clinical activity was observed during the dose escalation phase when administered as salvage line therapy including patients with prior FLT3 inhibitors (AACR2023). Based on these results the Committee for Orphan Medicinal Products released its positive opinion stating that “the drug showed responses in heavily pretreated patients with acute myeloid leukaemia including those who have failed treatment with the currently authorized medicinal product. The Committee considered that this constitutes a clinically relevant advantage.”

After having completed Phase I in Europe, the trial is currently enrolling patients in multiple Phase II cohorts (NCT03922100).

"*As we expand our focus to embrace the orphan drug destination in the EU for NMS-03592088, following the ODD approval by FDA last December, we are determined to bring new therapies to AML patients. Our dedication to innovation for patients worldwide is strong .*" said **Lisa Mahnke**, MD, PhD, CMO of NMS | CEO and Managing Director of NMS-US.

“*We are diligently implementing strategies to accelerate the development of NMS-03592088 as a promising new therapeutic option for patients battling AML with very few options. The Orphan Drug Designation is a key regulatory milestone that acknowledges the potential of NMS-03592088 for positioning as next generation FLT3 inhibitor and reinforces our commitment to expedite its development through the approval process*” said **Elena Ardini**, MSc, Asset Leader of NMS.

Orphan drug designation in the European Union (EU) is granted by the European Commission based on a positive opinion issued by the European Medical Association (EMA) Committee for Orphan Medicinal Products. The EMA grants orphan designation for the treatment, diagnosis or prevention of life-threatening or chronically debilitating diseases or conditions that affect fewer than five in 10,000

persons in the EU. Drugs that meet the EMA's orphan designation criteria qualify for financial and regulatory incentives that include a 10-year period of marketing exclusivity in the EU after product approval, reduced regulatory fees, access to protocol assistance from the EMA during development and access to centralized marketing authorization.

About Nerviano Medical Sciences

Nerviano Medical Sciences S.r.l. (NMS Srl) is focused on discovery and clinical development of small molecule NCEs for oncology. We take innovative approaches on novel mechanisms of action and drug targets to bring first- and best-in-class personalized medicines to cancer patients. Our current pipeline consists of NCEs, which all originate from our well validated kinase platform that span from early preclinical to clinical stage projects and which are being developed both in house and with partners.

NMS Srl combines the flexibility of a biotech with the quality of a big pharma. Here, an experienced management team leads a highly skilled staff of professionals with global vision and a broad range of expertise in research, drug discovery and clinical development. We cover the whole range of additional aspects of drug development through the NMS Group affiliate companies, Accelera (AdMet) and NerPharMa (manufacturing).

A key strength is our industrially renowned kinase inhibitor drug discovery platform which comprises an ever-evolving chemical collection with broad intellectual property coverage, discovery know-how and technologies which enabled us to out-license IP rights on recently approved innovative medicines such as encorafenib and entrectinib.

We collaborate with academia and clinical investigators as well as with industrial partners worldwide to advance our programs from early discovery to clinical development of new drugs. We seek further strategic collaborations to develop and commercialize our products in different territories as well as in-licensing opportunities of promising assets for clinical development.

About NMS Group

NMS Group is the largest oncological R&D company in Italy. With more than 400 employees of whom more than half are highly educated individuals dedicated to innovative research, development and manufacturing. The NMS kinase inhibitor discovery platform as well as the antibody-conjugating payload platform are the driving forces of the group's innovation, securing global recognition of NMS in personalized therapy. Recently entrectinib, originally discovered by NMS, is a targeted kinase inhibitor to treat NTRK1/2/3 and ROS1 dependent solid tumors that was licensed to Ignyta, now a member of the Roche Group, gained approvals for commercialization in all major markets. This is further evident of the competitiveness of the drug discovery platform of NMS Group.

NMS Group has three subsidiaries. NMS S.r.l. is a FIC / BIC focused drug research and development company with a robust pipeline of more than a dozen of anti-cancer projects, and three of the projects are currently in early clinical development. The other two subsidiaries are Accelera, which is a preclinical CRO company, and NerPharMa which manufactures API and drug product supporting clinical developments and commercialization.

Media Relations: sidney.dung@nervianoms.com