PRESS RELEASE

NERVIANO MEDICAL SCIENCES

PART OF NMS GROUP

Nerviano Medical Sciences received Orphan Drug Designation for its next-generation FLT3 inhibitor NMS-03592088 for treatment of Acute Myeloid Leukemia

NERVIANO, IT and BOSTON, Mass, 9 January, 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 the US Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for its next-generation FLT3 inhibitor NMS-03592088 for the treatment of Acute Myeloid Leukemia (AML).

NMS-03592088 is a potent inhibitor of FLT3, KIT and CSF1R that is being assessed as new therapeutic option for AML patients who are relapsed or refractory after treatment with prior standard of care drugs including prior FLT3 inhibitors. Preclinical characterization demonstrated that NMS-03592088 has superior features with respect to approved FLT3 inhibitor drugs supporting its positioning as next generation FLT3 inhibitor. Notably, in addition to the higher biochemical and cellular potency and superior in vivo efficacy, NMS-03592088 showed potent activity in the presence of the gatekeeper resistance mutation F691L, reported as cause of relapse after treatment with first generation FLT3 inhibitors opening the potential for treatment of patients who failed prior FLT3 inhibitor treatment.

The clinical efficacy of NMS-03592088 is being evaluated as monotherapy in a Phase I/II study in Europe and the US. Preliminary evidence of activity was observed during Phase I dose escalation with efficacy demonstrated in patients who had failed prior standard of care including patients who failed prior FLT3 treatments (LINK: AACR2023). The trial is currently enrolling patients in Phase II with different FLT3 positive AML settings explored (NCT03922100).

"*The orphan drug designation for NMS-03592088 is a significant achievement for NMS. It underscores the potential of NMS-03592088 and our dedication to making a difference in the lives of patients with FLT3 AML. We are proud to be at the forefront of innovation and remain steadfast in our mission to address unmet medical needs*" said **Lisa Mahnke**, MD, PhD, CMO of NMS | CEO and Managing Director of NMS-US.

"*Receiving orphan drug designation for NMS-03592088 is a critical milestone in our development journey. This recognition not only highlights the scientific merit of our approach but also reinforces our commitment to bringing novel therapies to those who need them most. We look forward to advancing NMS-03592088 through further clinical development and regulatory milestones*" said **Elena Ardini**, MSc, Asset Leader of NMS.

The FDA's Office of Orphan Products Development grants ODD status to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases or conditions affecting

fewer than 200,000 people in the United States. ODD provides benefits to drug developers designed to support the development of drugs and biologics for small patient populations with unmet medical needs. These benefits include potential for market exclusivity for seven years upon FDA approval eligibility for tax credits for qualified clinical trials, and waiver of Prescription Drug User Fee Act Application fee.

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.

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