PRESS RELEASE

NERVIANO MEDICAL SCIENCES
PART OF NMS GROUP

Nerviano Medical Sciences Announces FDA Clearance of Investigational New Drug (IND) for NMS-03592088 in positive Relapsed or Refractory Acute Myeloid Leukemia

*Nerviano 22 June 2023*_Nerviano Medical Sciences Srl (NMS), a member of NMS Group and a clinical stage company discovering and developing innovative therapies for the treatment of cancer, is delighted to announce the **FDA Clearance of** Investigational New Drug (IND) Application for NMS-03592088 (NMS-088), a novel, potent FLT3 inhibitor.

NMS-088 is poised to transform the landscape of FLT3 inhibitor by addressing a critical unmet medical need. It offers a breakthrough solution that has the potential to improve patient outcomes and significantly enhance quality of life. The IND approval enables NMS to advance to the next stage of clinical development, initiating critical trials to evaluate the safety, efficacy, and therapeutic potential of this next-generation FLT3 inhibitor.

"We are incredibly proud of this IND approval, which underscores our commitment to innovation and improving patient care," said Lisa Mahnke, MD, PhD, CMO of NMS. "This milestone is a testament to the hard work, dedication, and scientific expertise of our talented team. We remain steadfast in our mission to bring forth groundbreaking solutions that make a real difference in the lives of patients."

The forthcoming clinical trial will be conducted in partnership with renowned medical centers and institutions as part of NMS's global program. This collaborative approach ensures the rigorous evaluation and comprehensive assessment of NMS-088's safety, efficacy, and potential benefits across diverse patient populations.

As NMS moves forward with clinical trials, the company remains committed to adhering to the highest ethical and regulatory standards. Patient safety and well-being will remain paramount throughout the entire process, with careful monitoring and adherence to strict protocols.

About Acute Myeloid Leukemia
Acute Myeloid Leukemia (AML) is a rapidly progressing hematologic malignancy that most frequently develops in older adults. FLT3 mutations occur in approximately 30% of AML patients and are associated with aggressive disease, higher relapse rates and worse survival. Despite the approval of FLT3 inhibitors midostaurin and gilteritinib the prognosis of patients with relapsed or refractory disease is poor.

About NMS-03592088
NMS-03592088 is a novel, potent inhibitor of FLT3, KIT and CSF1R, all relevant targets in AML. NMS-03592088 showed superior preclinical activity compared with approved FLT3 inhibitors in different FLT3-driven models. In addition, NMS-03592088 is active on FLT3 gatekeeper mutation F691L causing resistance to first generation FLT3 inhibitors. NMS-03592088 is being developed in AML with two studies currently recruiting (MKIA-088-001 and MKIA-088-002)

About Nerviano Medical Sciences

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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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