PRESS RELEASE

NERVIANO MEDICAL SCIENCES
PART OF NMS GROUP

Nerviano Medical Sciences S.r.l. Announces First Patient Dosed in Phase 1 Clinical Trial of NMS-812 for The Treatment of Relapsed Refractory Multiple Myeloma (MM).

NERVIANO, July 19, 2022 – Nerviano Medical Sciences S.r.l., a member of NMS Group and a clinical stage company discovering and developing innovative therapies for the treatment of cancer, recently announced that the first patient has been dosed in its Phase 1 clinical trial of NMS-812 in adult patients with relapsed refractory Multiple Myeloma (MM).

NMS-812 is a novel potent oral inhibitor of PERK (PKR-like endoplasmic reticulum kinase) that also inhibits GCN2 (General Control Nonderepressible 2). PERK and GCN2 are effectors of the Integrated Stress Response (ISR), a pro-survival pathway exploited by cancer cells to survive stress. PERK is a key effector of the unfolded protein response (UPR) and GCN2 is a sensor of amino acid deficiency. Both proteins modulate the eIF2α/ATF4 axis promoting tumor survival and drug resistance as well as, via direct and indirect mechanisms, the immune response.

“PERK/GCN2 targeting has strong potential as an anti-cancer mechanism. NMS is pleased to mark this first patient milestone for the PERKA-812-001 program which, the company plans to develop in various malignancies hoping to address many important clinical questions in patients where there is an unmet need,” said NMS Chief Medical Officer Lisa Mahnke, M.D., PhD.

About the PERKA-812-001 Clinical Program

This is a Phase 1, first-in-human (FIH), open-label, non-randomized, multi-center study to explore the safety, tolerability, pharmacokinetics and preliminary antitumor activity of NMS-812 in adult patients with relapsed refractory Multiple Myeloma (MM) who have exhausted standard treatment options or for whom standard therapy is considered unsuitable.

The study includes a dose escalation and expansion phase and will enroll up to a total of 65 participants. Once the dose is identified, the dose expansion will include two arms, one arm with NMS-812 as single agent and the other one with NMS-812 in combination with dexamethasone. Visit clinicaltrials.gov (NCT05027594) for more details.

About NMS-812 in Multiple Myeloma

NMS-812 is an extremely potent, orally available inhibitor of PERK and GCN2, key regulators of the ISR, with potential for first-in-class. Cancer cells are subjected to extrinsic and intrinsic stress conditions, which result in UPR/ISR activation as a survival mechanism. Notably, tumors arising from professional secretory cells, such as MM, have a constitutively activated UPR, therefore PERK inhibition leads to MM cancer cell death due to proteotoxicity. Based on preclinical data, PERK inhibition may represent a novel effective strategy to inhibit the growth of these tumors as well as other types of tumors, with potential synergism with current SOC such as proteasome inhibitors in MM.

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, More than half of whom 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 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 products supporting clinical developments and commercialization.

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