PRESS RELEASE

NERVIANO MEDICAL SCIENCES

Nerviano Medical Sciences Presents Preliminary, Encouraging Clinical Phase 1 Data for PARP-1 Selective Inhibitor at the 35th AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics

NERVIANO, IT and BOSTON, Mass, October 12, 2023 - Nerviano Medical Sciences S.r.l., a part of NMS Group S.p.A. (NMS Group) and Nerviano Medical Sciences, Inc., a wholly owned subsidiary of NMS Group, focused on the discovery and early development of oncology drugs and the largest oncological R&D company in Italy, reported today, initial results from the dose escalation parts of two Phase I-I/II studies for NMS-03305293 (NMS-293). As an oral, brain penetrant PARP-1 selective inhibitor, NMS-293 has shown strong antitumor activity and complete tumor regression in BRCA mutated preclinical models as a single agent. NMS-293 shows remarkable selectivity towards PARP-1 and efficiently inhibits cellular PARP activity resulting in selective antiproliferative responses on BRCA mutated cell lines. Furthermore, NMS-293 is synergistic and well tolerated in combination with temozolomide (TMZ) in both MGMT methylated and MGMT unmethylated glioblastoma mouse models. For the first time, clinical data is being presented during the poster session (Abstract 37568) at the AACR-NCI-EORTC 2023 Annual Meeting in Boston, Massachusetts. The poster will be available today on the NMS websites.

“The data presented today shows NMS-293 is well tolerated and exhibits early signs of clinical activity, that together could provide future treatment options in areas of high unmet medical need in many non-BRCA-mutation tumors, including glioblastoma” stated Lisa Mahnke, MD, PhD, Chief Medical Officer for Nerviano Medical Sciences. NMS-293 showed encouraging clinical activity in combination with TMZ in difficult-to-treat, recurrent glioma patients. Investigator assessed clinical activity included two patients with relapsed glioma experiencing partial responses by RANO criteria as well as one patient with relapsed glioblastoma having disappearance of a non-measurable lesion.

NMS-293 is being evaluated in two Phase I-I/II dose-escalation/expansion studies assessing safety, tolerability, and preliminary antitumor activity. In PARPA-293-001 (NCT04182516), NMS-293 has been administered orally in dose escalation as a single agent, in adult patients with selected advanced/metastatic, relapsed/refractory solid tumors who have exhausted standard treatment options. An MTD has been identified at 100 mg BID for 28 days on 28-day cycle, a dose providing exposure in a meaningful, active range relative to preclinical predictions. PARPA-293-002 (NCT04910022) is a Phase I/II trial in which NMS-293 was administered in dose escalation, on days 1-7, together with TMZ for the first 5 days of each cycle, in repeated 28-day cycles in adult patients with recurrent diffuse gliomas who failed prior standard of care. The Phase II expansion will focus on glioblastoma. “I am so proud of our NMS team; NMS was the first company to crack PARP-1 biology and bring a PARP-1 selective inhibitor into the clinic. Furthermore, NMS is the first company to have a brain penetrant PARP-1 in clinical development. The initial clinical data presented in glioma is the first demonstration of our therapeutic hypothesis that a PARP-1 inhibitor can be combined with chemotherapy such as TMZ paving the way for indications outside of BRCA mutant tumors,” stated Hugues Dolgos, PharmD, Chief Executive Officer for NMS Group.

To date, no DLTs in PARPA-293-002 have been characterized, and overall, NMS-293 was well tolerated with no trends of myelosuppression. The unpooled safety database at the data-cut-off includes 45 patients in PARPA-293-001 and 21 patients in PARPA-293-002. The most frequent (≥10%) any-grade treatment related adverse events (TRAEs) in PARPA-293-001 were reversible QTcF prolongation, nausea, asthenia, decreased appetite and vomiting, mainly mild/moderate. In PARPA-293-002, no TRAEs above grade 3 were reported and the most frequent (≥10%) any-grade TRAEs were: nausea, fatigue, vomiting, decreased appetite, and decreased platelet count, mainly grade 1 adverse events.

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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