PRESS RELEASE

NERVIANO MEDICAL SCIENCES
PART OF NMS GROUP

Nerviano Medical Sciences S.r.l. Announces Collaboration and Option to License Agreement with Merck

NERVIANO, 21 September 2022 – Nerviano Medical Sciences S.r.l. (NMS), a member of the NMS Group and a clinical stage company discovering and developing innovative therapies for the treatment of cancer, announced today the signing of a collaboration agreement with licensing option with Merck Healthcare KGaA (Merck), for the next-generation highly selective and brain penetrant PARP1 inhibitor NMS-293.

PARP (poly (ADP-ribose) polymerase) is key in the repair of DNA damage and PARP inhibitors have been shown to be highly efficacious in the treatment of tumors deficient in homologous recombination repair, such as breast, ovarian, prostate and pancreatic cancers which are BRCA mutated.

NMS-293 is an orally available PARP1 inhibitor, designed to be more PARP1 selective and brain penetrant compared to first generation PARP inhibitors. With its expected lower hematological side effect profile, it has the expected features for potential use not only as single agent but also in combination with DNA-damage accumulating agents in a wide range of tumors. NMS-293 is currently in early clinical development for the treatment of patients with BRCA mutated tumors as single agent and with recurrent Glioblastoma (GBM), a brain tumor with very high medical need, in combination with temozolomide (TMZ).

Under the current agreement, Merck will make early payments (up-front and option exercise fees) of up to US$65 million to NMS. Furthermore, NMS will receive payments for the achievement of certain development, regulatory and commercial milestones and tiered royalties on net sales by Merck. Upon exercise of the option, NMS will grant to Merck the exclusive rights to research, develop, manufacture, and commercialize NMS-293.

“NMS-293 is the first next-generation PARP1 inhibitor to enter clinical trials. Based on its unique features, NMS-293 has strong potential in combination with a wide variety of DNA-damage accumulating agents, such as chemotherapy, DNA repair inhibitors or ADCs, in tumor settings that are precluded to current PARP inhibitors, such as brain tumors, and where there is an urgent global need to find treatments,” stated Hugues Dolgos, Pharm.D., chief executive officer of NMS and NMS Group. “NMS has built a unique and proprietary platform of first-in-class and best-in-class assets and expanded to new target classes like PARP with NMS-293 as our flagship. We believe that Merck, a global leader in DNA repair with a well-established commercialization footprint, is the ideal partner to maximize the value of our program.”

“Building on the therapeutic impact that PARP inhibitors have had over the last several years, we believe this new PARP1 program, if successful, could fill a significant unmet need for patients unresponsive to existing PARP inhibitors with an improved hematological adverse event profile,” said Victoria Zazulina, M.D., Head of Development Unit Oncology for the Healthcare business of Merck. “The work of NMS to discover and advance this next generation PARP1 selective inhibitor coupled with our deep expertise in

developing therapies which modify DNA damage response mechanisms, creates a strong foundation to further develop this investigational therapy for patients."

During the option period, NMS and Merck will collaborate on the clinical development of NMS-293 as monotherapy and in combination, with NMS designing, sponsoring, conducting, and funding global clinical trials.

About NMS-293

NMS-293 is an orally available small molecule inhibitor of PARP1 and is currently in early clinical development for the treatment of patients with BRCA mutated tumors as single agent and with recurrent Glioblastoma (GBM), a brain tumor with very high medical need, in combination with temozolomide (TMZ).

About Nerviano Medical Sciences

Nerviano Medical Sciences S.r.l. (NMS Srl) is focused on discovery and clinical development of small-molecule new chemical entities (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 originating 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. Our 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. More than half of our 400 employees 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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