PRESS RELEASE

NERPHARMA
PART OF NMS GROUP

**FOR IMMEDIATE RELEASE**

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BrYet Health Inc starts a Manufacturing Development Agreement with NerPharMa for its lead product candidate ML-016 against lung and liver metastases from different type of breast cancer.

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BrYet is an American biotechnology company based in Houston TX founded for the purpose of developing and bringing to market drugs for prevention and treatment of multiple types of metastatic cancer, based on a disruptive approach developed by Prof. Mauro Ferrari: Transport Oncophysics.

BrYet will collaborate with our strategic production partner NerPharMa, a leading CDMO in oncology, to scale-up the drug substance manufacturing process and the finished product to supply material for clinical programs with potential upside to future world-wide commercial sales. The company's goal is to start ML-016 clinical trials in the second half of 2023.

ML-016 is a multi-component drug (iNPG-pDox), with each component being designed to achieve penetration across a set of sequential biological barriers, and with what would conventionally be considered the "active principle" being a simple, generic chemotherapeutic agent. This provides a time sequence of actions, including selective bio-barrier penetration, and cytotoxic actions against therapy-resistant cancer cells. The target localization is obtained through preferential permeation through the sequence of cancer-modified biological barriers, essentially through physics-based approaches (Xu et al., Nat. Biotechnol., 2016, 34, 414-420; Goel et al., Sci. Adv. 2020; 6: eaba4498). From the study, unprecedent survival rate was observed in mice bearing tumors in the lung after treatment with ML-016. ML-016 is the first-in-class, physics-based drug, effectively ushering in a new era of cancer therapeutics. Many novel drugs are expected to arise from transport oncophysics, that comprise chemotherapeutic elements (like ML-016), and other types of active ingredients.

NerPharMa, part of NMS Group runs GMP manufacturing facility approved by both the Italian Medicines Agency (AIFA), the national authority responsible for drug regulation in Italy, and the U.S. Food and Drug Administration (FDA). Its solid track record, unparalleled expertise, professional and agile approach stands out as the best partner to accelerate our speed to market.

"This contract is a significant step in our development of ML-016," said Mauro Ferrari, President and CEO of BrYet. "We are pleased to have secured access to GMP production of drug substance and finished product to start our clinical program, EU and USA registration strategy, as well as potential expansion for future commercial activities in an US FDA and EU approved manufacturing facility."

"We are pleased and honored to work with BrYet installing their innovative technology in our premises. Our strong know-how in oncology will be beneficial to the scale-up and development of their manufacturing processes; I am confident that we will be able to provide new and innovative anti-cancer drugs to patients in the near future" said Angelo Colombo, CEO of NerPharMa.

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**About BrYet**

BrYet is an American biotechnology company based in Houston TX founded for the purpose of developing and bringing to market drugs for prevention and treatment of multiple types of metastatic cancer, based on a disruptive approach developed by Prof. Mauro Ferrari: Transport Oncophysics. This breakthrough technology provides a time sequence of actions, including selective bio-barrier penetration, and cytotoxic actions against therapy-resistant cancer cells.
Many novel drugs are expected to arise from transport oncophysics, that comprise chemotherapeutic elements (like ML-016, the first-in-class multi-component drug), and other types of active ingredients.

**About NerPharMa**

NerPharMa owns a wide and cutting-edge organizational structure able to manage and handle highly active compounds, and to ensure the full development and production of active principles and finished products intended for the world market as well as the research and development of innovative formulation and delivery systems. The two divisions in NerPharMa, NerPharMa DS (drug substance) and NerPharMa DP (drug product), operate in accordance with Current Good Manufacturing Practices (cGMP) and are authorized by the most relevant authorities: Italian Drug Agency (AIFA), U.S. Food and Drug Administration (FDA), ANVISA Brazil, China FDA, PMDA Japan and Russia for the production of both pharmaceutical active ingredients and finished products.

**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.
The NMS Group has three subsidiaries. NMS srl 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.