

Entrectinib, the kinase inhibitor drug initially discovered and developed by Nerviano Medical Sciences approved by AIFA in two oncology indications

Nerviano, 14 September 2021_ Entrectinib, the kinase inhibitor drug that was initially discovered and developed by Nerviano Medical Sciences (a member of NMS Group) and that is now marketed by Roche and partners, has received approval for marketing and reimbursement from the Italian drug agency AIFA in two oncology indications: lung cancer ROS1 kinase fusion positive, and any solid tumor type with NTRK kinase gene fusions.

Entrectinib was originally invented and developed into a drug product at Nerviano. It is highly active against tumors with rearranged forms of either one of the three kinases called ALK, ROS, and TRK, and its initial Phase I study, which started in 2012, was conducted at two major hospitals in Milan – the IRCCS Istituto Nazionale dei Tumori (INT) and the Niguarda Cancer Center. This first-in-human (FIH) study generated some of the key data later used to obtain worldwide marketing approval of the drug in the two different oncological indications, with patient selection based on molecular defects in the NTRK and ROS genes.

Entrectinib, designed to efficiently cross the blood brain barrier in order to treat ROS1-rearranged lung cancer patients with CNS metastases, demonstrated a high level of efficacy in such patients – a key factor for its approval in this type of cancer. Also, with entrectinib NMS provided the first clinical evidence that NTRK gene fusion products, present at a low but significant frequency in several different tumor types, represent a druggable target for solid tumors – a finding which later led to the marketing approval of one of the first precision medicine drugs to receive an agnostic indication (approval for use against any type of tumor with a given genetic context and independently from the tissue origin), i.e. that for use against NTRK rearranged solid tumors.

The success of the Phase I clinical study of entrectinib initiated by NMS led to a collaboration with the biotech Ignyta, who continued clinical development of the drug in a global Phase II registration trial, prior to being acquired by Roche. Receiving several regulatory authority approvals between 2019 and 2020 in various major geographic regions, entrectinib is now marketed worldwide by Roche and partners. We are very proud to communicate that on 14 September 2021 the Italian drug regulatory agency AIFA approved entrectinib for marketing and reimbursement in its homeland.

Link to the Roche press release in Italian: [Tumori: è made in Italy la terapia intelligente | Roche Italia](#)

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About Nerviano Medical Sciences

[Nerviano Medical Sciences S.r.l.](#) is focused on discovery and clinical development of small molecule NCEs for oncology. The company takes 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 oncology drug discovery platform that span from early preclinical to clinical stage projects and which are being developed both in house and with partners.

Nerviano Medical Sciences S.r.l. 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. Moreover, we are also developing a proprietary payload platform for generation of novel Antibody-Drug Conjugates (ADCs).

NERVIANO MEDICAL SCIENCES

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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 evidence 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.

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