Nanobiotix completes patient inclusion for Phase II/III trial of NBTXR3 in soft tissue sarcoma

Paris, France and Cambridge, Massachusetts, USA, October 23, 2017 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, today announced that it has completed patient inclusion for the Phase II/III trial (Act.In.Sarc) of its lead product candidate, NBTXR3, in soft tissue sarcoma. The last patients are expected to start their treatment in two to three weeks.

Elsa Borghi, Nanobiotix’s Chief Medical Officer commented: “We are pleased to have reached this important milestone in Nanobiotix’s soft tissue sarcoma study, and we look forward to reporting our first data next year.”

The pivotal international Phase II/III study in soft tissue sarcoma was launched in Europe and Asia in October 2014 and aims to evaluate the safety and the efficacy of NBTXR3, a first-in-class radio-enhancer that could potentially target most solid tumors. The Phase II/III study is a prospective, randomized, multi-center, open label and active controlled two-arm study of 156 patients with locally advanced soft tissue sarcoma.

The trial’s primary endpoint is the complete pathological response rate. The secondary endpoints are the objective response rate (ORR) by imaging (MRI); the evaluation of the safety profile in terms of clinical and laboratory adverse events; the tumor volume changes; the resection margins and the limb amputation rate. Furthermore, an exploratory analysis of the progression free survival is planned once the follow-up period has been completed for all treated patients.

Nanobiotix expects to present the results of its Phase II/III trial in soft tissue sarcoma in the first half of 2018.

For more information about the study: Clinical trial.gov and http://www.actinsarc.com/.

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About NANOBIOTIX: www.nanobiotix.com

Nanobiotix (Euronext: NANO / ISIN: FR0011341205) is a late clinical-stage nanomedicine company pioneering novel approaches for the treatment of cancer. The Company’s first-in-class, proprietary technology, NanoXray, enhances radiotherapy energy with a view to providing a new, more efficient treatment for cancer patients.

NanoXray products are compatible with current radiotherapy treatments and are meant to treat potentially a wide variety of solid tumors including soft tissue sarcoma, head and neck cancers, liver cancers, prostate cancer, breast cancer, glioblastoma, etc., via multiple routes of administration.

NBTXR3 is being evaluated in: soft tissue sarcoma (STS), head and neck cancers, prostate cancer, and liver cancers (primary and metastases). Additionally, head and neck cancer and rectal cancer trials led by Nanobiotix’s Taiwanese partner, PharmaEngine, are underway in the Asia Pacific region. The Company filed in August 2016 for market approval (CE Marking) in Europe for its lead product NBTXR3.

In 2016 the Company started a new preclinical research program in Immuno-oncology with its lead product NBTXR3, which could have the potential to bring a new dimension to cancer immunotherapies.

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This press release contains certain forward-looking statements concerning Nanobiotix and its business. Such forward-looking statements are based on assumptions that Nanobiotix considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the reference document of Nanobiotix filed with the French Financial Markets Authority (Autorité des Marchés Financiers) under number D.17-0470 on April 28, 2017 (a copy of which is available on www.nanobiotix.com) and to the development of economic conditions, financial markets and the markets in which Nanobiotix operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Nanobiotix or not currently considered material by Nanobiotix. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Nanobiotix to be materially different from such forward-looking statements.

This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, Nanobiotix shares in any country. At the moment NBTXR3 does not bear a CE mark and is not permitted to be placed on the market or put into service until NBTXR3 has obtained a CE mark.