EXPANDED ACCESS POLICY
US REGULATORY REQUIREMENT

Nanobiotix is a clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer. Nanobiotix's first-in-class, proprietary lead technology, NBTXR3, aims to expand radiotherapy benefits for millions of cancer patients.

NBTXR3 is actively being evaluated in several clinical trials : treating patients with locally advanced head and neck squamous cell carcinoma (HNSCC), with hepatocellular carcinoma (HCC) or liver metastases, locally advanced or unresectable rectal cancer in combination with chemotherapy, head and neck cancer in combination with concurrent chemotherapy, and prostate adenocarcinoma. Nanobiotix is also running an Immuno-Oncology development program and has a large-scale, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center (9 new phase I/II clinical trials in the United States) to evaluate NBTXR3 across head and neck, pancreatic, thoracic, lung, gastrointestinal and genitourinary cancers.

Nanobiotix uses the data it collects from clinical trials to prepare marketing applications to The United States Food and Drug Administration (FDA) and other regulatory bodies. FDA has granted a Fast Track designation to the investigation of NBTXR3 activated by radiation therapy, with or without cetuximab, for the treatment of patients with locally advanced head and neck squamous cell cancer who are not eligible for platinum-based chemotherapy.

In this regulatory frame, Nanobiotix communicates its expanded access policy in USA for NBTXR3.

What is expanded access?

Through expanded access, sometimes referred to as compassionate use, patients may be able to access investigational new drugs outside of the clinical trial context. FDA will typically facilitate expanded access to investigational products for patients with serious or life-threatening conditions, or whose life is immediately threatened by their disease or condition when no comparable or satisfactory alternative therapy options are available. Unlike the use of an investigational new drug in a clinical trial setting, the primary purpose of expanded access is to use the investigational drug for patient treatment purposes, rather than to gather data on safety and effectiveness.

What is Nanobiotix's policy on expanded access?

Nanobiotix believes that investigational drugs should be studied in patients as part of clinical trials designed to obtain data on safety and efficacy that may be used to support approval of the product and subsequent wider accessibility to patients.

As a general policy, pre-approval access outside of a controlled clinical trial may interfere with the conduct of ongoing trials and may also disrupt the progress of the overall development program, which in turn could delay access to many other patients in need.

Nanobiotix development resources are focused on conducting clinical studies required by regulatory authorities to fully answer important scientific questions about the potential risks and benefits of our investigational product (NBTXR3), and to obtain regulatory approval.

For all of the aforementioned reasons, Nanobiotix has reached the difficult decision to not accept expanded access requests at this time. This policy is subject to change at the discretion of Nanobiotix and this document will be updated should there be a change.

How can I get more information?

For more information on clinical trials, see https://clinicaltrials.gov. Search “Nanobiotix” to find Nanobiotix clinical trials that may currently be recruiting. If you are a healthcare professional and would like more information on Nanobiotix’s investigational product (NBTXR3), please send an inquiry to medinfo@nanobiotix.com.