Nanobiotix announces 18.1 month median overall survival for 41 evaluable elderly and frail patients with HNSCC in phase I expansion evaluating NBTXR3 as a single agent activated by radiotherapy

October 24, 2021

Data presented by Professor Christophe Le Tourneau at the 2021 Annual Meeting of the American Society for Radiation Oncology

- First survival data from Phase I Dose Expansion in tough-to-treat elderly and frail LA-HNSCC patients ineligible for cisplatin and intolerant to cetuximab:
  - Median Overall Survival of 18.1 months in evaluable patients (n=41) and median Progression Free Survival of 10.6 months
  - Best observed target lesion objective response rate of 85.4% and best observed target lesion complete response rate of 63.4%[1]
  - NBTXR3 administration was feasible and well tolerated in population with significant burden of disease and comorbidity
- Phase I dose expansion data support and inform the design of upcoming phase III global registration trial in a larger HNSCC population with lower comorbidities overall

Paris, France; Cambridge, Massachusetts (USA); October 24, 2021 – NANOBIOTIX (Euronext: NANO – NASDAQ: NBTX – the " **Company**) **,** a late-stage clinical biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer, today announced first ever survival data from its priority head and neck cancer development program at the 2021 Annual Meeting of the American Society for Radiation Oncology (ASTRO).

As specified by the ASTRO Annual Meeting embargo policy, "information beyond what is included in the abstract, such as updated or additional results, is embargoed until the date and time of scientific presentation or presentation at an ASTRO news briefing, whichever occurs first." However, Nanobiotix has become aware that ASTRO made a late decision to release the posters at the same time as the abstracts and did not sufficiently update the embargo policy. As a result, the Company is releasing this data in advance of its intended embargo date.

New Data from Locally Advanced Head and Neck Squamous Cell Carcinoma (LA-HNSCC) Program

Data show a median Overall Survival (mOS) of 18.1 months and a median Progression Free survival of (mPFS) of 10.6 months in the evaluable population (n=41) from the dose expansion part of its phase I, multicenter, open-label, non-randomized dose escalation and dose expansion study evaluating NBTXR3 as a single-agent activated by radiotherapy in tough-to-treat elderly and frail LA-HNSCC patients ineligible for cisplatin and intolerant to cetuximab (Study 102 Expansion). In the full population (all evaluable and non-evaluable patients treated; n=54), data showed a 14.1-month mOS and a 9.4-month mPFS. The data suggest that lower mOS and mPFS observed in the full population versus the evaluable population in the study could be related to early death associated with high burden of comorbidity in the non-evaluable population.

Evaluability in Study 102 Expansion was determined based on the patient receiving at least 80% of the intended intratumoral dose of NBTXR3, at least 60 Gy of radiotherapy, and the required imaging to assess the target lesion at baseline and at least once post treatment.

Response rates remained consistent with previously reported results from the dose escalation and dose expansion study, showing a best observed target lesion objective response rate (ORR) of 85.4% and a best observed target lesion complete response rate (CRR) of 63.4%[2].

Figure 1: Best Observed Target Lesion Response by RECIST 1.1 as per Investigator Assessment

image

"I have held the belief that NBTXR3 could have a real impact for patients with solid tumors since reviewing the proof-of-concept data from the phase II/III in soft tissue sarcoma and throughout my participation in Study 102 Expansion," said study principal investigator Professor Christophe Le Tourneau, senior medical oncologist and head of the Department of Drug Development and Innovation (D3i) at Institut Curie. "This first look at survival data has added to my confidence that NBTXR3 could provide a promising new therapeutic option for the practice. I look forward to leading the upcoming phase III global registration study, and to have the opportunity to evaluate the promise of this innovation in a larger patient population."

Of the 21 evaluable patients with a best observed overall response of complete response (CR) with a mean follow-up of 16.1 months, 6 patients died for non-oncologic reasons and only one died from disease progression.

NBTXR3 administration was feasible and well-tolerated overall. A total of 8 Grade 3-4 NBTXR3-related adverse events (AEs) were observed in 8 patients, representing 1.3% of all observed AEs. Of these AEs related to NBTXR3, 5 serious adverse events (SAEs) were observed including dysphagia, sepsis, soft tissue necrosis, stomatitis, and tumor hemorrhage. Of the SAEs, one death from sepsis assessed by the investigator as possibly related to NBTXR3, radiotherapy, and cancer was observed.

While the incidence of LA-HNSCC has continued to rise, patients in the elderly and frail LA-HNSCC population have significant unmet needs. Many are not eligible to receive concurrent chemoradiation due to frailty associated with comorbidities. The modified Charlson Comorbidity Index (mCCI) is a measure of comorbidity burden on a patient-by-patient basis, and high mCCI (i.e., mCCI ≥ 4) is correlated with higher risk of death relative to the broader population. In this study, 63% of all patients treated had high mCCI, which is two to three times the prevalence of comorbidity in the overall LA-HNSCC population[3].

Despite the prevalence of high mCCI in Study 102 Expansion, these preliminary data support further evaluation of NBTXR3 activated by radiotherapy as a therapeutic option that may translate to a survival benefit for elderly and frail LA-HNSCC patients. The data also suggest that the potential benefits of the therapy could improve in a population with a lower burden of comorbidity.

“Bringing innovation to the patients that need it most has always been the backbone of our development strategy for NBTXR3,” said Laurent Levy, co-founder and chief executive officer of Nanobiotix. “We started with soft tissue sarcoma—a disease indication notoriously resistant to radiotherapy. After proving we could provide a therapeutic benefit versus radiotherapy alone for patients with locally advanced disease and achieving European market approval, we pivoted to patients with locally advanced head and neck cancer that have substantially limited treatment options. The new survival data we are seeing from Study 102 Expansion bolster our confidence in the promise of NBTXR3 as we near the launch of our pivotal phase III study in head and neck cancer. We have designed this study with the benefit of our learnings from the phase I and look forward to the opportunity to prove that our product candidate can expand treatment possibilities for patients with cancer around the world.”

[1] Calculations include one patient marked ** in Figure 1 assessed as Complete Response by principal investigator per eCRF

[2] Calculations include one patient marked ** in Figure 1 assessed as Complete Response by principal investigator per eCRF

[3] Zumsteg ZS, et al., Cancer 2017;123:1345-53

About NANOBIOTIX
Nanobiotix is a late-stage clinical biotechnology company pioneering disruptive, physics-based therapeutic approaches to revolutionize treatment outcomes for millions of patients; supported by people committed to making a difference for humanity. The company’s philosophy is rooted in the concept of pushing past the boundaries of what is known to expand possibilities for human life.

Incorporated in 2003, Nanobiotix is headquartered in Paris, France. The company also has subsidiaries in Cambridge, Massachusetts (United States), France, Spain, Germany and Switzerland.
Nanobiotix has been listed on the regulated market of Euronext in Paris since 2012 and on the Nasdaq Global Select Market in New York City since December 2020.

Nanobiotix is the owner of more than 30 umbrella patents associated with three (3) nanotechnology platforms with applications in 1) oncology; 2) bioavailability and biodistribution; and 3) disorders of the central nervous system. The company's resources are primarily devoted to the development of its lead product candidate– NBTXR3 —which is the product of its proprietary oncology platform and has already achieved market authorization in Europe for the treatment of patients with soft tissue sarcoma under the brand name Hensify®.

For more information about Nanobiotix, visit us at www.nanobiotix.com or follow us on LinkedIn and Twitter.

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Source: Nanobiotix