NB-013: TLR9 Agonist CpG-ODN LNP for Solid Tumors

Proprietary CpG-ODN LNP formulation functioning as a TLR9 agonist designed to reinvigorate anti-tumor immunity.

NB-013: TLR9 Agonist CpG-ODN LNP for Solid Tumors

A Clinical-Stage Intratumoral Immunotherapy

An intratumoral TLR9 agonist designed to potently activate cellular immunity within the tumor microenvironment. With dual IND approvals from both the FDA (January 2025) and CDE (March 2025), it is poised to enter first-in-human trials in the near term across multiple advanced solid tumor indications including HNSCC, Sarcoma, and Osteosarcoma. Phase 1 first-in-human trials are imminent, with Phase 2 initiation anticipated in late 2026.

- Preclinical data demonstrate potent activation of cellular immunity, converting immunologically "cold" tumors to "hot" tumors
- Designed as a potential PD-(L)1 combination therapy to improve checkpoint inhibitor response rates
- Phase II clinical trial initiation anticipated in late 2026

Core Active Ingredient

CpG-ODN (Qtolimod) — a potent TLR9 agonist that activates innate and adaptive cellular immunity for tumor immunotherapy

QTsome Delivery System

Proprietary lipid nanoparticle platform for intratumoral injection, significantly improving local retention and systemic safety profile

Dual IND Approvals

FDA IND approved Jan 18, 2025; CDE IND approved March 2025 — enabling parallel US and China clinical development

NB-013: TLR9 Agonist CpG-ODN LNP for Solid Tumors

A Clinical-Stage Intratumoral Immunotherapy

A proprietary lipid nanoparticle (LNP) formulation of CpG-ODN (Qtolimod), a potent TLR9 agonist designed for intratumoral injection in patients with advanced solid tumors. By activating innate and adaptive cellular immunity within the tumor microenvironment, NB-013 converts immunologically "cold" tumors to "hot," and is designed as a combination partner for PD-(L)1 checkpoint inhibitors.

Proven Preclinical Efficacy

Robust tumor growth inhibition demonstrated in three syngeneic models (MC38, B16-F10, K7M2); survival advantage confirmed vs. vehicle controls

Favorable Safety Profile

30-fold safety window above max intended clinical dose; localized PK with drug essentially undetectable in blood and peripheral tissues

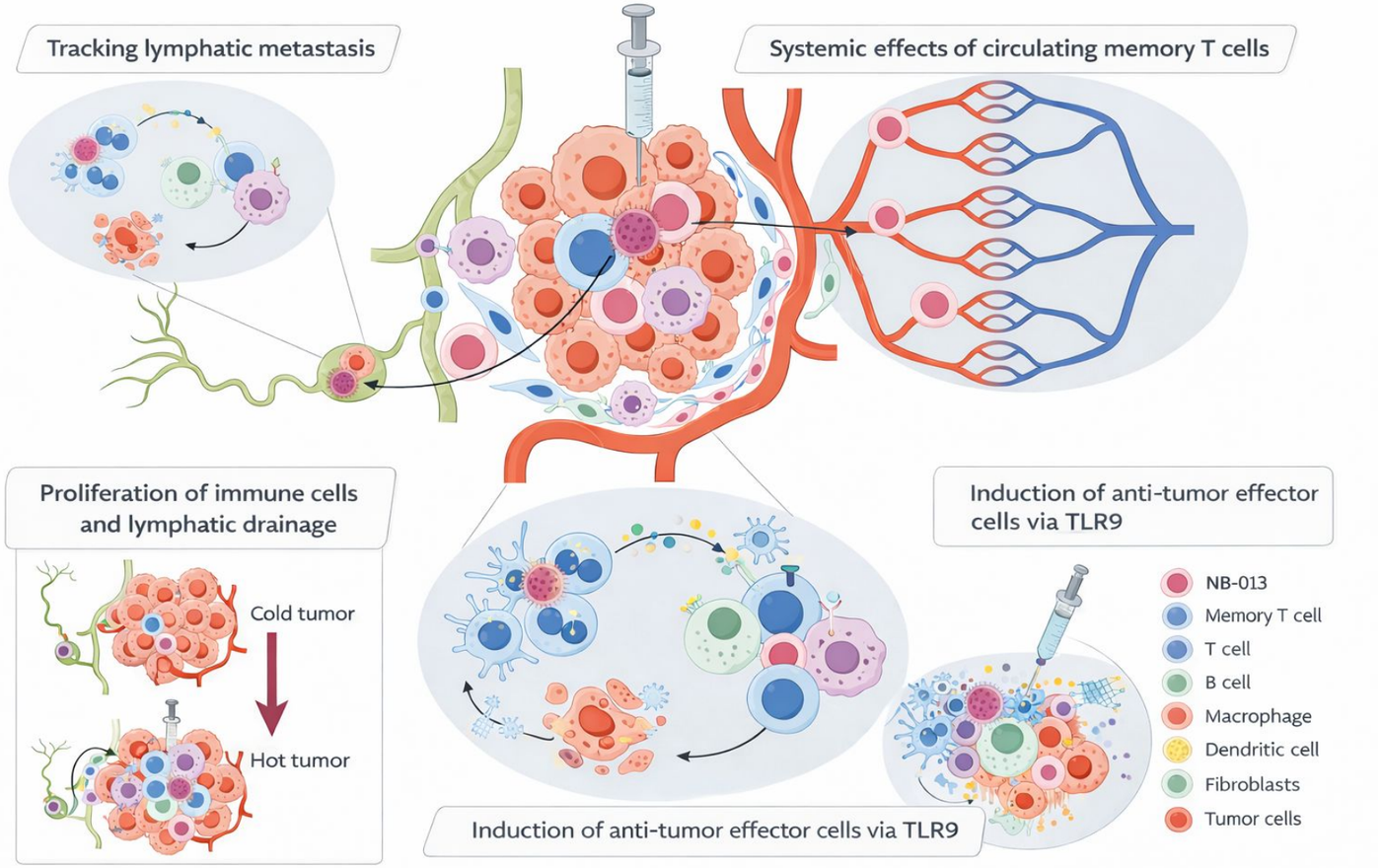
Near-Term Clinical Milestones

Phase 1 FPI (China, Dec 2025), US site startup underway; Phase 2 planned late 2026

NB-013: TLR9 Agonist CpG-ODN LNP for Solid Tumors

Potential PD-1 Companion Drug for Enhancing Immune Response

NB-013's core active ingredient, CpG-ODN (Qtolimod), is a synthetic TLR9 agonist that triggers innate immune activation, maturation of dendritic cells and recruitment of cytotoxic T lymphocytes. By engaging TLR9 signaling within the tumor microenvironment, NB-013 stimulates the generation of systemic anti-tumor memory T cells, converting immunologically "cold" tumors to "hot." The proprietary QTsome delivery system ensures drug retention at the injection site while minimizing systemic exposure, greatly improving the safety profile relative to unformulated CpG-ODN.



Clinical Development Timeline

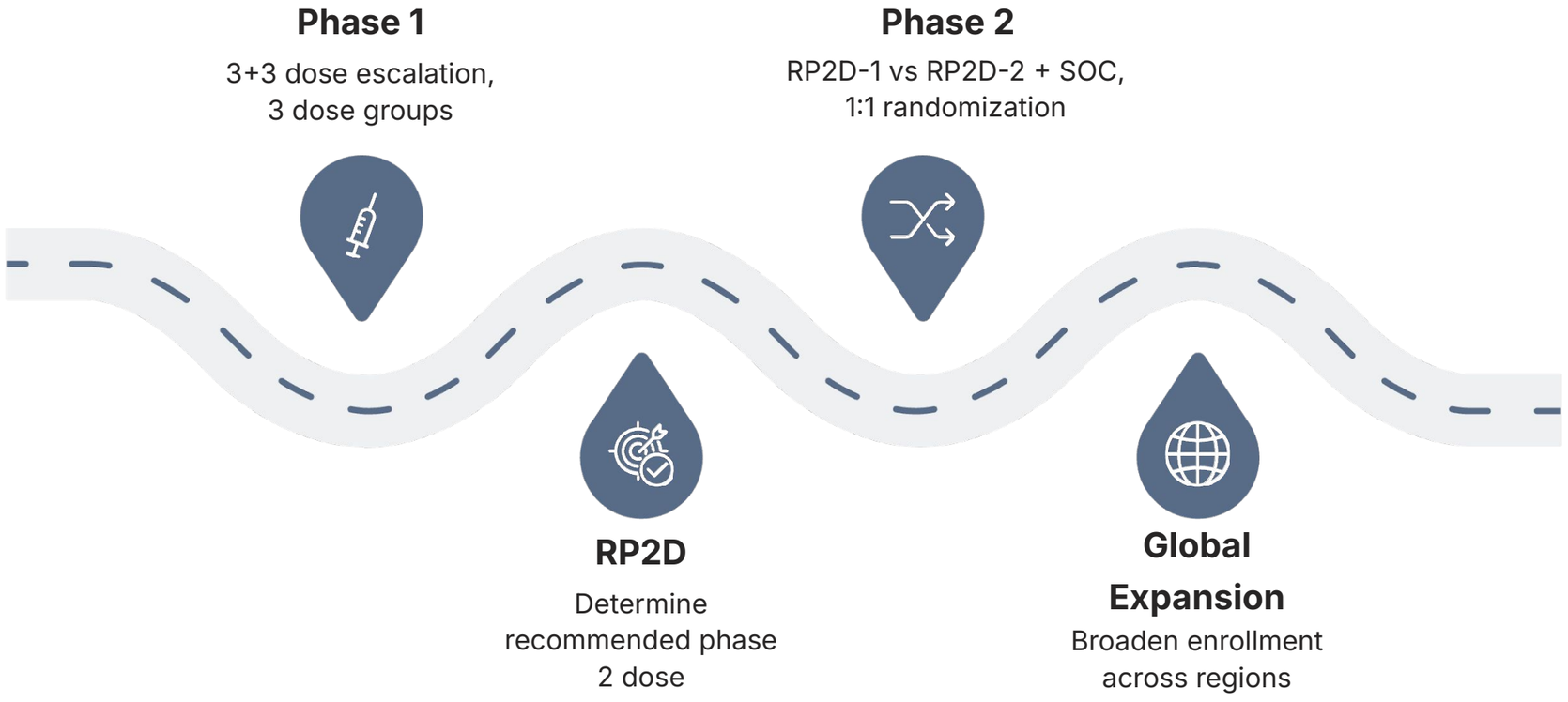
China: First Patient In (FPI) expected December 2025, indications include MM, HNSCC and Sarcoma

United States: Site Startup (SSU) documentation underway from November 2025, with osteosarcoma as a lead indication

NB-013: TLR9 Agonist CpG-ODN LNP for Solid Tumors

Phase 1 Trial: Study Design

A Phase 1 study assessing the safety and preliminary efficacy of the Lipid Complex Injection via intratumoral administration in patients with advanced or relapsed solid tumors. The study employs a classic "3+3" dose-escalation design across three dose cohorts to establish the Recommended Phase 2 Dose (RP2D), followed by a randomized Phase 2 expansion.



China Mainland Program

Indications: **Multiple Myeloma (MM), Head & Neck Squamous Cell Carcinoma (HNSCC), and Sarcoma (SARC)**.

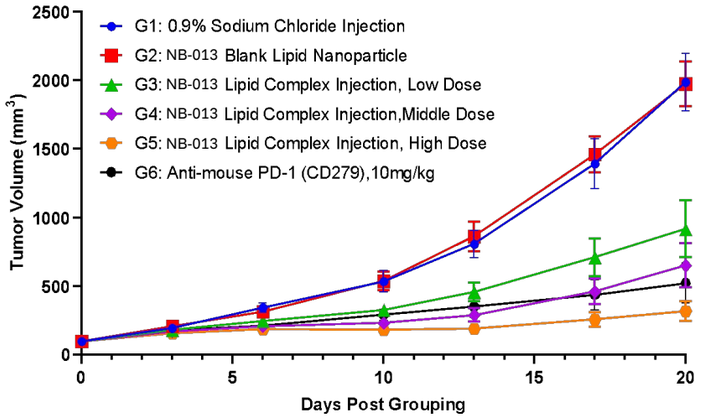
United States Program

Focused on **solid tumors with emphasis on osteosarcoma** — an area of significant unmet need. Study Start Up (SSU) documentation preparation is ongoing as of November 2025.

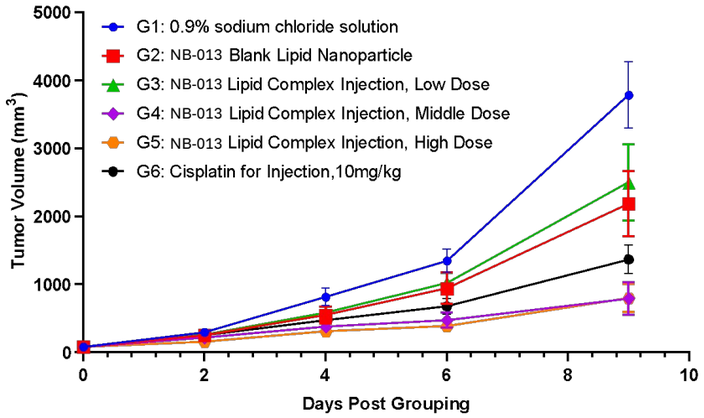
NB-013: TLR9 Agonist CpG-ODN LNP for Solid Tumors

Pre-Clinical Data: Anti-Tumor Efficacy as Monotherapy

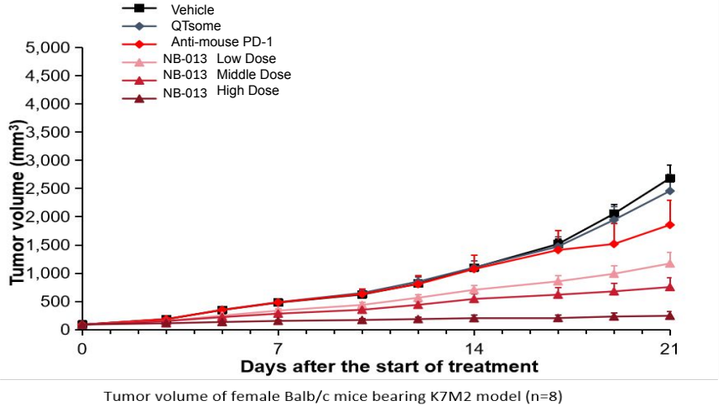
In three distinct syngeneic tumor models — MC38 (colorectal), B16-F10 (melanoma) and K7M2 (osteosarcoma) — intratumoral administration of NB-013 demonstrated robust tumor growth inhibition and conferred a meaningful survival advantage compared to vehicle controls. These results establish broad-spectrum anti-tumor activity supporting the clinical investigation of NB-013 across multiple solid tumor types.



Tumor volume curves in MC38 model (n=8)

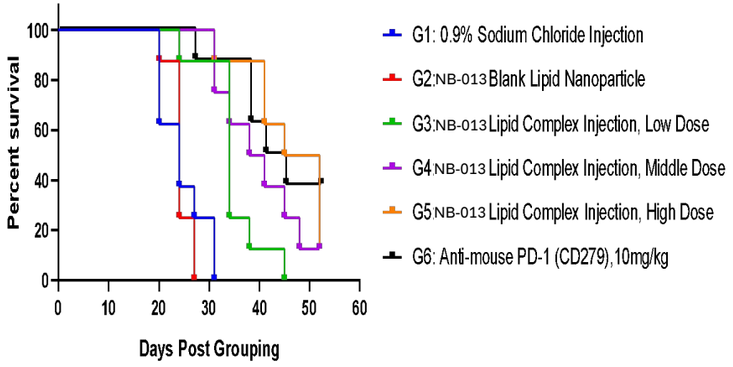


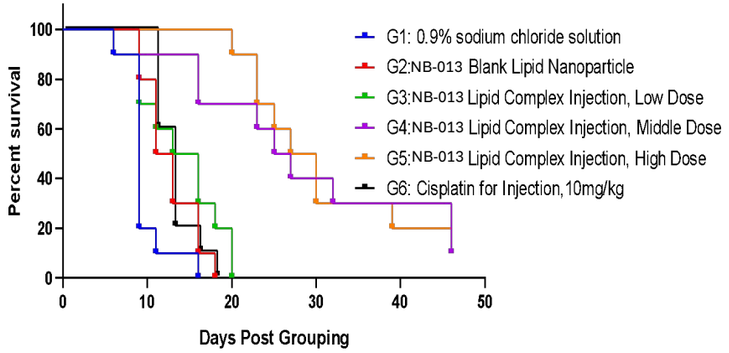
Tumor volume curves in B16-F10 model (n=10)

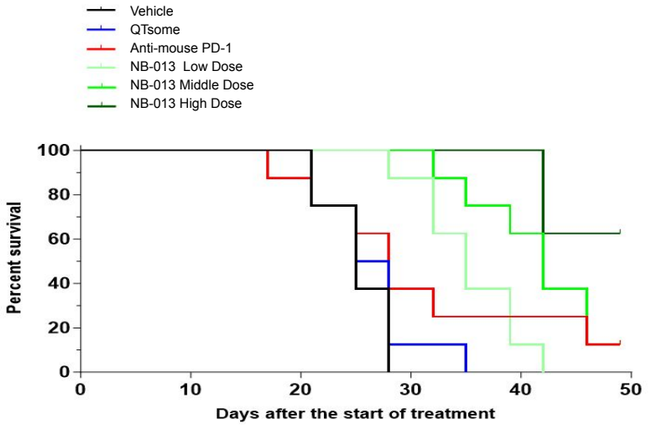


Tumor volume of female Balb/c mice bearing K7M2 model (n=8)

Tumor volume curves in K7M2 model (n=8)







NB-013: TLR9 Agonist CpG-ODN LNP for Solid Tumors

Pre-Clinical Data: PK Profile and Safety Data

Pharmacokinetic Profile

Drug predominantly distributed at the administration site (tumor tissue) with levels **essentially undetectable in blood and peripheral tissues**

Drug concentrations remained detectable in tumor tissue for up to **168 hours (7 days)** post-dosing, supporting a weekly administration schedule

- Favorable local retention supports the intratumoral injection approach and minimizes systemic exposure

GLP Toxicology Summary

GLP 4-week repeat-dose + 4-week recovery studies conducted in **mice and cynomolgus monkeys**

Well tolerated; safety window of **at least 30-fold** above the maximum intended clinical dose

- No significant CNS effects (mice) or cardiovascular/respiratory effects (monkeys)
- No hERG channel inhibition; no hemolysis in rabbits; no allergic reactions in guinea pigs within clinical dose range
- Local irritation observed at injection site in both species — expected and manageable

The 30-fold safety window above the maximum intended clinical dose, combined with localized PK distribution, supports a favorable risk-benefit profile for intratumoral administration in early-phase clinical trials.

Accelerating Innovation to Improve Patients' Lives

Navika Bio connects groundbreaking biotech innovation with global pharmaceutical partners to deliver transformative therapies to patients worldwide.

NAVIKA BIO

Let's Connect

For more information about partnership opportunities and to join us on this exciting journey of bringing transformative therapies to patents worldwide, please reach out to:

Lawrence Hu, PhD

Chief Technology Officer
Head of Business Development

Phone: 973-967-9949

Email: lawrence@navikabio.com