

Ntrust-2 fact sheet for healthcare providers



Title of study A Study of NKX019, a CD19 Chimeric Antigen Receptor Natural Killer (CAR NK) Cell Therapy, in Subjects with Immune-Mediated Disease

About NKX019 Natural killer (NK) cells derived from the peripheral blood of healthy adult donors are expanded and modified to produce NKX019, which is then available for off-the-shelf, on-demand dosing. NKX019 exhibits approximately 10-fold greater cytotoxicity compared to non-engineered NK cells against CD19+ cell lines in vitro.¹ Unlike T cells, NK cells do not rely on expansion after administration for their activity and do not typically result in severe expansion-related toxicities.

¹ Morisot N, Wadsworth S, David T, et al. Preclinical Evaluation of NKX019, a CD19-targeting CAR NK Cell. *J Immunother Cancer*. 2020 Nov 1;8:A140.

Study participants To be eligible for this study, participants must be 18 to 70 years old and meet key inclusion criteria, including classification/diagnosis of:

- Systemic sclerosis (SSc or scleroderma) with inadequate response or intolerance to at least 1 treatment or
- Probable or definite (> 55%) idiopathic inflammatory myopathy (IIM or myositis) and refractory disease, defined as ≥ 6 months failure (or intolerance) to at least 2 immunosuppressive therapies or
- Relapsed or refractory antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV or polyangiitis) despite repeated treatment with immunosuppressive agents or requiring prolonged and/or repeated courses of unacceptable doses of glucocorticoids to maintain disease control

Key objectives

- Assess safety and tolerability of NKX019
- Assess preliminary clinical activity of NKX019 in participants with SSc, IIM, or AAV
- Characterize pharmacokinetics and immunogenicity of NKX019

Study periods The Ntrust-2 study will consist of 4 periods for each participant as follows:

- **Screening** – Participant eligibility determined over a period of up to 45 days
- **Active Treatment** – Conditioning with lymphodepletion followed by NKX019 on Days 0, 3, and 7
- **Follow-Up** – From Day 27, study visits every 30 days through Month 6, then every 90 days through Year 2
- **Extended Follow-Up** – Yearly survival and safety survey (Years 2–15)

For more information, you and your patients can visit Ntrust2.com.

To refer a patient directly, please contact:

