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 75 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 (including corticosteroids) or • Relapsed or refractory antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV or polyangiitis) despite adequate treatment with at least 1 immunosuppressive agent or requiring prolonged and/or repeated courses of unacceptable doses of glucocorticoids to maintain disease control or • Rheumatoid arthritis (RA) with inadequate response or intolerance to at least 1 conventional synthetic disease-modifying antirheumatic drug (DMARD) and either at least 2 biologic DMARDs with distinct mechanisms of action or at least 1 biologic DMARD and at least 1 targeted synthetic DMARD
Key objectives	• Assess safety and tolerability of NKX019 • Assess preliminary clinical activity of NKX019 in participants with SSc, IIM, AAV, or RA • 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** – Assessments at protocol-specified intervals 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:

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