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NKGen Biotech and HekaBio enter strategic partnership to bring novel NK cell therapy to Japan

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US-headquartered NKGen Biotech, Inc. a clinical-stage biotechnology company focused on the development and commercialisation of innovative autologous and allogeneic natural killer (NK) cell therapeutics, and Japan-based HekaBio K.K., have announced a strategic partnership to accelerate the regulatory, manufacturing and commercial development of NKGen's autologous NK cell therapy, troculeucel, in Japan following HekaBio's recently announced investment in common equity of NKGen.

HekaBio will lead all clinical trials in Japan and oversee all regulatory activities with Japan's Pharmaceuticals and Medical Devices Agency for pre-market approval of troculeucel in several neurodegenerative disease indications, including Alzheimer's and Parkinson's Diseases.

As troculeucel is an autologous, non-genetically modified cell therapy, there is allowance under regenerative medicine regulations in Japan to offer this therapy to patients on an accelerated path, much faster than in other major markets.

HekaBio will fully leverage the regulation and its domestic strategic partner network, aiming for first dosing in Japanese patients over the next 12 months. Beyond intractable disease, troculeucel has the potential to also support Japan's ageing population in the longevity/wellness space.