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# First in Human Clinical Study Demonstrating the Safety and Efficacy of NK101 (supercharged NK cells) in the Treatment of Patients with Cancer

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**Abstract**

Natural killer (NK) cells are well-known to lyse tumor cells, but their anti-tumor activity is impaired in tumor microenvironment. In addition, the lack of adequate expansion and decreased persistence in cancer patients and diminished function, with the existing strategies have hampered the field and has shown little efficacy in clinical trials. Moreover, the reduced number and function of NK cells in cancer patients has led to a lower success rate in developing adaptive treatment using autologous NK cells. To overcome these problems, we designed a cancer immunotherapeutic strategy using allogeneic healthy donor-derived supercharged NK cells (NK101). We previously have demonstrated the preclinical efficacy and safety of NK101 in tumor-bearing humanized-BLT mice. In this presentation, we report the results of the first two cancer patients and one patient suffering from deep vein thrombosis (DVT) infused with NK101. The therapy demonstrated an excellent safety profile, with no adverse side effects or any discomfort to either patient post-infusion. In contrast, patients reported an unusual increase in energy levels, disappearance of aches and pains and increase in well-being. Patients were monitored for 180 days post-therapy, and post-infusion blood analysis of patients revealed a positive immune response in the absence of any kind of adverse safety events. Post-infusion clinical presentation revealed early signs of clinical efficacy, with several validated data points confirming NK101's ability to target and significantly decrease the tumor load in cancer patients. In addition, the percentages and function of NK cells rose in patients significantly and remained high for the duration of the studies. The early clinical findings are consistent with preclinical results obtained using NK101 cells that demonstrated the ability to arrest tumor progression and restore immune function.