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## ***Ex vivo*-expanded allogeneic NK cells for treatment of refractory and recurrent lymphoma and solid tumors**

**Yu Kyeong Hwang**

Green Cross LabCell, South Korea

Allogeneic NK cells have been used for their activity for hematologic cancer by hematopoietic stem cell transplantation. During the last decades, anti-cancer activity of *ex vivo* expanded NK cells were demonstrated in several studies, both *in vitro* and *in vivo*. Previously, *ex vivo* expanded allogeneic NK cells (MG4101) from healthy unrelated donor showed potent anti-tumor activity with tolerable toxicity profiles in several xenograft models. From healthy donor's peripheral blood mononuclear cells (PBMCs), NK cells expanded under good manufacturing practice (GMP) conditions. NK cells selectively killed cancer cells without demonstrating cytotoxicity against allogeneic non-tumor cells in co-culture assays, and show the anti-tumor activity in various cancer model including lymphoma, ovarian cancer, hepatocellular carcinoma, neuroblastoma and glioblastoma. Phase I clinical trial had been conducted in 18-advanced and refractory cancer patients with various solid tumor and lymphoma by dose-escalating infusing. No adverse effects were reported after, and changes of immune cell population and cytokine/chemokine levels were shown by NK cell infusion. Therefore, allogeneic NK cell treatment without T cell contamination is feasible for cancer patients, and good clinical outcome is expected if it is used with adequate preconditioning regimen. For more additive efficacies, two more clinical trials have been conducted in patient's solid tumor after HSCT and in HCC patients after curative resection. Both study showed its safety and delayed progress free survival (PFS) and recurrent free survival (TTP), respectively. Based on this NK cell manufacturing process, new genetically modifying technology like chimeric antigen receptor (CAR) technology can be emerged. NK cell is one of option to solve the problem in adverse effect in CAR-T therapy. In cooperation with many of advanced technology, NK cell therapy can be a new modality for the cancer treatment as an off-the-shelf product.

### **Biography**

Yu Kyeong Hwang has worked in pharmaceutical company driven research institute for more than 25 years. Her main interest is immune activation by antigen stimulation, many of candidate peptides and DNA constructs were listed in patents. Based on long term experience of cellular immunology in T cell area, since 2014, she is a Director of Cell Therapy Research Center in Green Cross LabCell (GCLC) Corp. By developing NK cell therapeutics, she controlled all process from discovery to clinical trials of *ex vivo* expanded allogeneic NK cell which was the world's first clinical trial. In the clinical trial phase I, she discovered the mechanism of allogeneic NK cell after infusion into patients. Currently this NK cell program goes on phase IIa against HCC. Another couple of clinical trials are preparing IND submission in Korea and US.

ykhwang@greencross.com

### **Notes:**