

Non-clinical Development of gene therapy drug candidates based on oncospreading retroviral vectors

[a:rtiCure]

Disease Area	Neoplasm
Product Type	Split, pseudotyped-Replicating Retroviral Vectors encoding two suicide genes
Indication	1 st indication: Glioblastoma 2 nd indication: Incurable neoplasms (TNB etc.)
Target	Proliferating tumor cells
Mechanism of Action	Expression of suicide genes (TK & CD) during replication in tumor cells and spread on tumor tissue > Treatment of prodrugs (GCV & 5-FC) > Induction of cancer cell-death and anti-tumor immunity
Competitiveness	<ul style="list-style-type: none">- Unlike oncolytic viruses. little immune reaction against the viral vectors- No early clearance of the viral vectors after injection- Minimized recombination during reverse transcription for viral replication- Can be armed with multiple therapeutic genes, such as suicide/cytokine/CAR-targeting genes without size limitation
Development Stage	Candidate (GLP-toxicity and GMP manufacturing)
Route of Administration	Intra-tumoral or into tumor bed (systemic injection: under developing)

In vivo Efficacy Evaluation

Syngeneic, orthotopic rat model (ARTI 101)

> 100% tumor eradication and survival (Group B)

A

B

Mouse xenograft model using human U87-MG cells

> 100% eradication and survival

Control group (spRCRe-TK/sRCRgp-RFP + PBS), 2 individuals

Treatment group (spRCRe-TK/sRCRgp-RFP + GCV), 3 individuals

In-House Safety Evaluation

Toxicity

Not observed

Biodistribution

Not detected in normal tissues

Shedding

Not detected

Integration site analysis

No insertional mutagenesis

Virus Producer Cells (VPC)

HSV1-TK virus VPC

Yeast CD virus VPC

GMP production finished

QC finished

Being used in process development

IP	<div>1. US 9,657,312 B2</div> <div>2. US 10,039,841 B2/GB2572716/CN 110225977 B/KR 10-1885438</div> <div>3. US 11,970,708 B2/GB2614168/JP7412832/Korea & China(under review)</div>
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