

# STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (MN-169)

LUTADENOVEC AUTOGENE

PRONUNCIATION

loo" tah den' oh vek aw' toe jeen

THERAPEUTIC CLAIM

Treatment of solid tumors

## DESCRIPTIONS

DNA (chimpanzee adenovirus 68-derived construct GRT-C901 viral protein gene E1 deletion plus viral protein gene E3 deletion plus viral protein gene E4 deletion-containing plus cytomegalovirus promoter plus transcription factor tetR (tetracycline repressor)-response element CMT plus tumor-specific neoantigen prototype cassette-expressing)

Self-amplifying mRNA (samRNA) vector based on Venezuelan equine encephalitis virus (VEEV). Sequences encoding the structural proteins of VEEV are deleted and replaced by a patient-specific cassette expressing 20 tumor-specific neoantigens (TSNAs). The vector encodes the VEEV proteins as well as the 5' and 3' RNA sequences required for RNA replication but encodes no structural proteins, so no infectious viral particle is formed. The VEEV subgenomic 26S promoter located 5' of the inserted TSNA cassette drives expression of the TSNAs. The patient-specific TSNA cassette is inserted into the GRT-R902 (pUC02-ATG-VEE-eGFP) backbone vector. This plasmid is used as a template to synthesize the drug substance by in vitro transcription, which is then formulated using lipid nanoparticles to make the patient-specific vaccine. The sequence of the TSNA cassette is different for each patient and is designed by the proprietary algorithm EDGE based on the tumor-specific information derived from each patient.

## SEQUENCE

### C901 Sequence

C901 is a ChAd-TSNA virus vector, which is used a prime for GRANITE-001 and is boosted with a self-amplifying mRNA, samRNA-R902, vaccine vector formulated in LNP. R902 also expressing the same TSNA cassette as C901. The TSNA cassette has been codon optimized for maximum expression in humans. The vaccine expression cassette begins with a sequence coding for the amino acids, methionine, alanine and glycine (MAG) and the 500 amino acid patient specific cassette is followed by a class II helper domain which consists of two universal class II helper epitopes, PADRE, the pan HLA DR-binding epitope, and Tetanus Toxoid P2 (830-844 amino acid of tetanus toxin Tc) epitopes linked by glycine and proline linkers (GPGPG).

### GRT-C901 Table of features

Relevant sequences are color coded in the actual sequence

Nucleotide region (position numbers & sequence annotation)	Region encodes	Comments	Sequence color
1-118	Left ITR		Red
594-1,252	CMT	Regulated CMV promoter with	Purple for CMV promoter with TET

		tetracycline (TET) operator	operator in black bold font
1,253-1,309	Intergenic region		Black
1,310-1,318	Initiation Sequence	MAG amino acid triplet	Blue
1,319-2,818	TSNA	Indicated by N sequence	Orange
2,819-2,950	Class II Domain	Includes PADRE & Tetanus Toxoid universal class II helper epitopes	Green
2,951-2,997	Intergenic region		Black
2,998-3,221	SV40 Poly A region		Pink
3,222-3,330	Intergenic region		Black
3,331-3759	Protein IX		Black
5,442-3,818	Protein IVA2		Black
13,679-13,671, 8,502-4,921	Polymerase (Pol)		Black
13,679-13,671, 9,882, - 8,301	pTP		Black
10,666-10,941	52K		Black
11,865-13643	pIIIa		Black
13,727-15,331	PIII		Black
15,332-15,913	PVII		Black
15,958-16,989	PV		Black
17,013-17,246	PX		Black
17,323-18,051	PVI		Black
18,158-20,959	Hexon		Black
20,980-21,600	Protease		Black
23,213-21,672	DBP		Black
23,242-25,656	100K		Black
25,367-25,700, 25,870-26,204	33K		Black
25,367-25,933	22K		Black
26,284-26,967	PVIII		Black
27,276-28,553	Fiber		Black
29,813-29,643, 28,908-28,660	E4ORF6/7		Black
29,813-28,908	E434K		Black
30,057-29,719	E4ORF4 with deletion	Deletion of first 27 NT of ORF4	Black
30,106-30,058	E4ORF2		Black
30,520-30,146	E4ORF1		Black
30,816-30,933	Right ITR		Light Green

### GRT-C901 sequence (30,933 bp)

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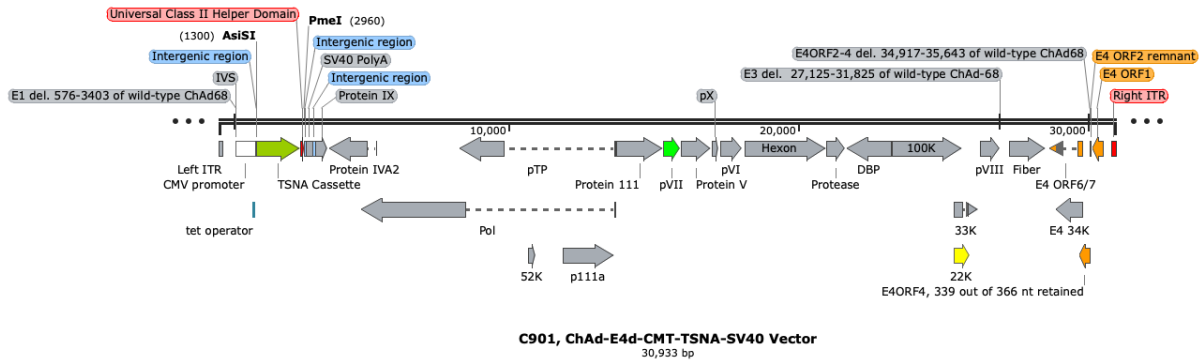
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## Schematic of C901 (ChAd68-TSNA) Map



SPONSOR	Gritstone Bio, Inc.
CAS REGISTRY NUMBER	2805319-15-5
CODE DESIGNATIONS	GRT-C901
UNII	H2D7GJ5FAW
WHO NUMBER	13100

SCS