		Solid Tumors				Lymphocytic/blastic Malignancies			Other Hematological Malignancies						HIV/ Infections	
		Minimal Residual Disease		Metastatic		Minimal Residual Disease	Acute/ Chronic	Metastatic	Minimal Residual Disease		Acute/ Chronic		Metastatic		Any Stage	
1 Pre-conditioning*	**Pre-conditioning**	+		+		+	+	+	+		+		+		+	
	IL-2 in Activation Cocktail	+	-	+	-	-	-	-	+	-	+	-	+	-	+	-
2 Infusion	Pure NK	+	+			+	+		+	+	+	+				
	Pure (NK + GDT)	-/+	-/+	+	+	+	-/+	+	+	+	-/+	-/+	+	+	+	+
	NK + GDT + iNKT	-/+	-/+	+	+	-/+	-/+	+	-/+	-/+	-/+	-/+	+	+	+	+
	NK + CD3			+	+			+						+	-/+	-/+
3 Post- infusion	*In Vivo* Activation with IL-2	+	-	+	-	-	-	-	+	-	+	-	+	-	+	-
	COX2 Inhibition	+		+		+	+	+	+		+		+		+	
	Other PGE2 Inh.	-/+		-/+		-/+	-/+	-/+	-/+		-/+		-/+		-/+	

FIGURE 1

Section 1 describes pre-conditioning for each patient, with IL-2 utilized in the activation cocktail for certain selected conditions, but not all.

* It is noted that certain regimens will include administering to the patient interferon-alpha (IFN-α), or a biological equivalent thereof, at a dosage of between about 1 X 10^6IU/m^2/d to about 10 x 10^6IU/m^2/d, two days and 1 day prior to administering the lymphocytic cellular composition comprising activated NK cells.

Section 2 describes four cellular infusion options where the therapeutic lymphocytic cellular compositions can be any of the following:

- activated NK cells;
- activated NK cells + activated GDT cells;
- activated NK cells + activated GDT cells+ iNKT;
- activated NK cells + CD3 T cells.

Section 3 describes post-treatment options, where COX2 inhibitors are given in all instances, *in vivo* activation with IL-2 is achieved in selected conditions, and other PGE2 inhibitors are administered optionally in certain conditions, as well.

FIGURE 2A

	Hemoglobin	HCT	RBC	WBC	Abs Neut	Abs Lymph	Abs Mono	Abs Eos	Alk Phos	AST	ALT	LDH	CD3+	% CD4	Abs CD4
Day -95	15.5	43.3	4.69	5,300	2,500	2,100	500	100	78	38	29			29.4	617
Day -35	13.7	40.8	4.32	6,600	4.1	2,000	300	100					1,168	28.6	572
Day -5	15	43.3	4.64	4,000	1,600	1,600	600	100	75	36	29			29	464
Day -2	13.2	38.5	4.1	4,800	2,300	1,700	600	100	72	57	31				
Day 0	13.3	39.8	4.14	3,300	1,800	1,000	400	100	64	26	24		893	23.4	234
Day 5	12.6	36.8	3.97	17,400	2,800	11,800	2,100	700	134	87	91	424	11,564	4.2	485
Day 6	12.6	37	4.02	17,900	2,000	12,000	3,000	700					11,124	5.6	672
Day 7	12.2	35.6	3.87	19,900	1,800	13,100	3,800	1,200					12,576	5.47	688
Day 8	12.5	36.1	3.91	8,400	1,600	5,100	700	900	123	168	96	343		20.45	
Day 9	12.9	37.8	4.1	7,300	2,600	3,100	1,000	700	137	77	151	332		24.25	
Day 10	12.8	37.4	4.02	7,400	2,900	2,900	800	700					2691	26.4	766
Day 13	13.7	42.3	4.47	5,100	2,100	1,500	700	600					1385	23.8	357
Day 17	12.2	36.3	3.91	5,400	1,600	2,000	1,000	700	101	40	38		1850	16.5	330
Day 28	12.9	38.7	4.07	3,800	1,600	1,400	400	300	81	35	26		1301	22.7	318
Day 35	12.7	38.5	4.1	4,800	2,400	1,400	500	500					1291	25.4	356
Day 44	14.3	41.5	4.36	6,900	4,400	1,700	600	200						33.3	533
Day 49	14.2	42	4.45	7,200	4,200	2,000	600	400						36	684

FIGURE 2B

	% CD8	Abs CD8	CD4/CD8	% CD3+CD25+	Abs CD3+CD25+	% CD8+CD38+	Abs CD8+CD38+	% CD8+HLA-DR+	Abs CD8+HLA-DR+	% GD T	% NK	HIV RNA copy/ml	HIV RNA Log10
Day -95	55.2	1,159	0.5323										
Day -35	54.6	1,092	0.5238	14.2	284	15.3	306	7.3	146				
Day -5	57.3	917	0.5059									25,930	4.414
Day -2													
Day 0	65.8	658	0.3556	10.8	108	47.7	477	16.1	161			40,640	4.609
Day 5	91.76	10,611	0.0451							1.24	7.49		
Day 6	87.2	10,464	0.0642	15.5	1860	83	9,960	82.1	9,852			255,900	5.408
Day 7	88.57	11,138	0.0617			85.24	10,719	79.61	10,011	1.48	6.49	65,480	4.816
Day 8	75.61		0.2704							2.11	5.46		
Day 9	69.13		0.3507							2.52	9.37	261,660	5.418
Day 10	65.7	1905	0.402	25.4	737	48.6	1409	25.2	731	3.47	10.49	55,580	4.744
Day 13	66.9	1004	0.355	18.6	279	47.1	707	21.9	329				
Day 17	75	1500	0.22	11	220	43.6	872	16.8	336			232,660	5.367
Day 28	68.3	956	0.33	15.5	217	46.6	652	23.2	325	4.67	9.19	6,790	3.832
Day 35	65.1	911	0.39	18	252	37.8	529	23.4	328			5,000	3.699
Day 44	60.1	962	0.554							5.67	13.49	2,210	3.344
Day 49	54.4	1033	0.662							6.22	12.99	<20	

FIGURE 3A

Number of Patients Treated

Metastatic Solid Tumors	# of patients
Colorectal cancer	1
Pancreatic cancer	2
Breast cancer	4
Ovarian cancer	2
Renal cell carcinoma	2

Hematological Malignancies	# of patients
Multiple myeloma	2
CLL	2

Infectious Disease	# of patients
HIV	2

FIGURE 3B

Representative Timeline Chart of a Treatment Protocol Example

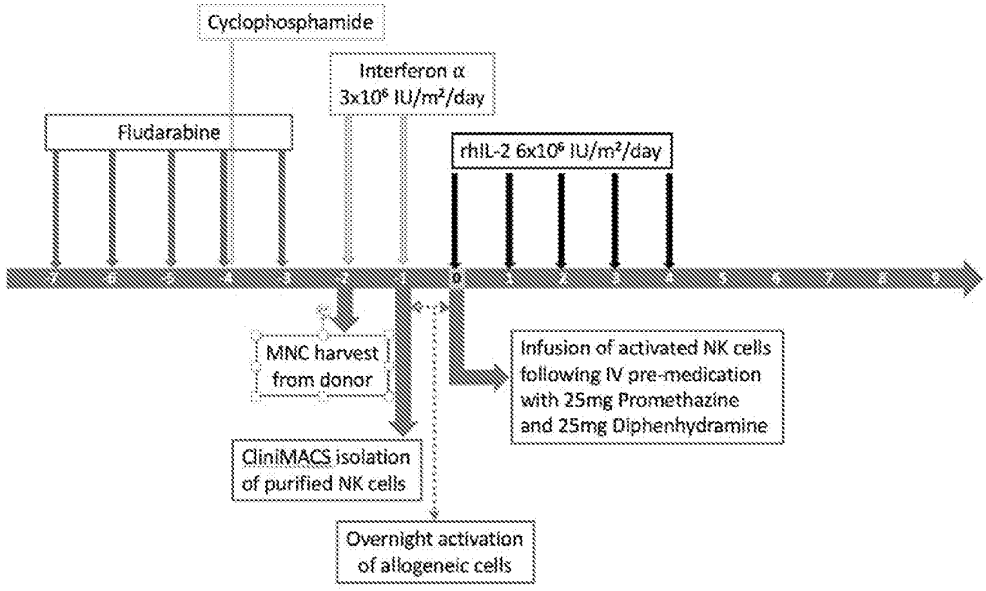


FIGURE 3C

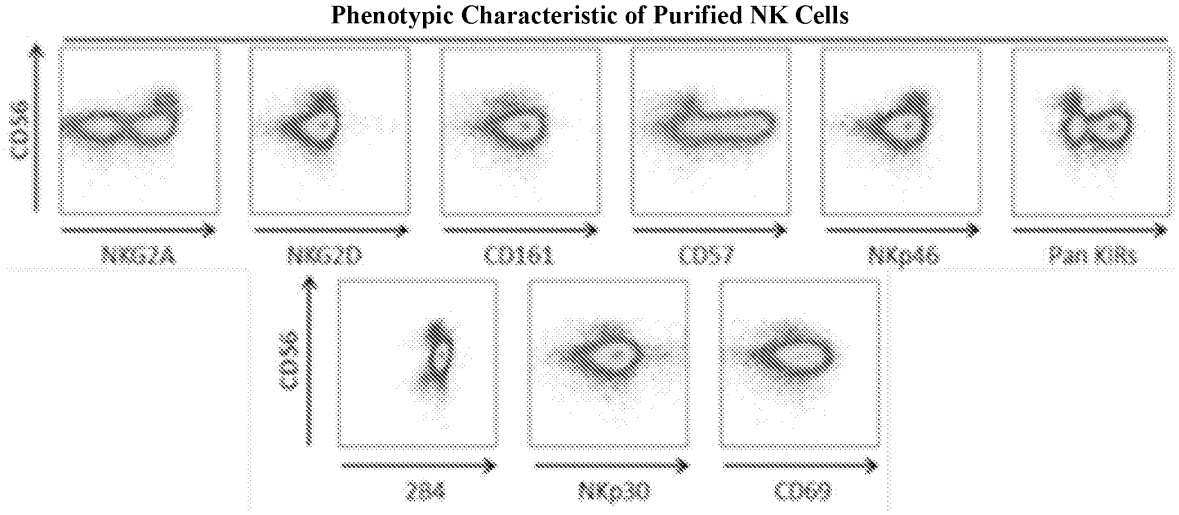


FIGURE 3D

Treatment Toxicity using WHO Criteria

	Grade I	Grade II	Grade III	Grade IV
Hemoglobin	9	4	0	0
WBC	10	3	2	0
Neutrophils	8	4	1	1
Platelets	5	4	2	0
Edema	3	1	0	0
Pericardial Effusion	2	1	0	0
Fever	4	9	2	0
Allergy/Hypersensitivity	6	2	0	0

FIGURE 3E

Survival of Patients (Solid and Hematological Malignancies)

	No. of Patients	Survival in months
Alive-PFS	10	>66 CRC, >74 PanC, >90 BC, >68 BC, >32 RCC, >102 OvC, >92 MM, >82 MM, >110 CLL, 48 CLL
Alive-SD	2	>22 BC, >18 RCC
Alive-PD	1	>12 OvC
Deceased	2	1-6 months

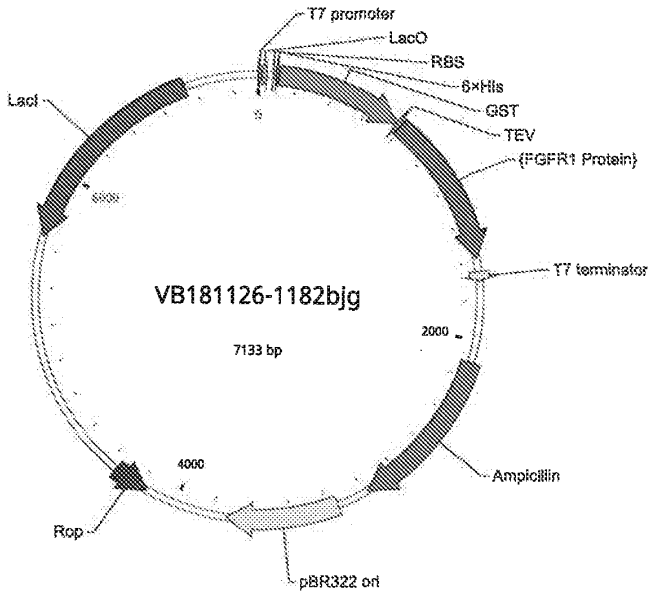
PFS= progression-free survival, SD= stable disease, PD= progressive disease, CRC =colorectal cancer, PanC =pancreatic cancer, BC= breast cancer, OvC= ovarian cancer, RCC= renal cell cancer, MM= multiple myeloma, CLL= chronic lymphocytic leukemia

Figure 4

Vector Summary

Vector ID	VB181126-1182bjg
Vector Name	pET-6×His/GST/TEV/{FGFR1 Protein}
Date Created (Pacific Time)	2018-11-26
Size	7133 bp
Vector Type	Bacterial protein expression vector pET
Inserted ORF	{FGFR1 Protein}
Plasmid Copy Number	Low
Antibiotic Resistance	Ampicillin
Expression Host	BL21(DE3)
Cloning Host	Stbl3 (or alternative strain)

Vector Map



Vector Components

Name	Position	Size (bp)	Type	Description	Application notes
T7 promoter	1-17	17	Promoter	T7 promoter	Drives high-level transcription of downstream gene in E. coli host cells that express T7 RNA polymerase; can also be used for in vitro transcription.
LacO	20-44	25	Miscellaneous	Lac operator	In the absence of IPTG, it is bound by lac repressor (LacI), leading to transcriptional repression of downstream gene. In the presence of IPTG, LacI can no longer bind to LacO, thus allowing downstream gene to be transcribed.
RBS	76-80	5	RBS	Ribosome binding site	Recruits ribosome to mRNA and aligns ribosome with start codon to initiate protein synthesis in E. coli.
6×His	91-108	18	Tag	6 tandem histidine tag	Facilitates purification by nickel or cobalt matrix and antibody binding of tagged protein.

Figure 4 Cont.

Name	Position	Size (bp)	Type	Description	Application notes
GST	109-765	657	Tag	Glutathione S-transferase	Facilitates purification by glutathione matrix and antibody binding of tagged protein; helps to stabilize tagged protein and protect it against intracellular protease cleavage.
TEV	766-786	21	Tag	Tobacco etch virus protease cleavage site	Cleaved by tobacco etch virus protease, which cuts after glutamine in the recognition sequence EXXYXQ(G/S) where X can be any amino acid.
(FGFR1 Protein)	787-1584	798	ORF	FGFR1 ECD	*None*
T7 terminator	1649-1695	47	terminator	T7 transcription terminator	Allows transcription termination of RNA transcribed by bacteriophage T7 RNA polymerase.
Ampicillin	2116-2976	861	ORF	Ampicillin resistance gene	Allows E. coli to be resistant to ampicillin.
pBR322 ori	3147-3735	589	Replication_origin	pBR322 origin of replication	Facilitates plasmid replication in E. coli; regulates low-copy plasmid number when Rop protein is presence (15-20) and median-copy plasmid number when Rop is absent (100-300).
Rop	complement (4162-4353)	192	ORF	Repressor of primer	It encodes a small protein that regulates plasmid copy number in E. coli. The presence of Rop protein, in combination with pBR322 origin of replication on the plasmid, results in low copy number of the plasmid.
LacI	complement (5665-6747)	1083	ORF	Lac repressor	In the absence of IPTG, it binds to lac operator (LacO) to repress transcription of downstream gene in E. coli. In the presence of IPTG, it no longer binds to LacO, thus allowing downstream gene to be transcribed.

Note: Components added by user are listed in bold red text.

Vector Sequence (SEQ ID NO: 1)

```
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 201 GTATGAGCGC GATGAAGGTG ATAAATGGCG AAACAAAAAG TTTGAATTGG GTTTGGAGTT TCCCAATCTT CCTTATTATA TTGATGGTGA TGTTAAATTA
 301 ACACAGTCTA TGGCCATCAT ACGTTATATA GCTGACAAGC ACAACATGTT GGGTGGTTGT CCAAAAGAGC GTGCAGAGAT TTCAATGCTT GAAGGAGCGG
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 501 GTTCGAAGAT CGTTTATGTC ATAAAACATA TTTAAATGGT GATCATGTAA CCCATCCTGA CTTCATGTTG TATGACGCTC TTGATGTTGT TTTATACATG
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 701 TAGCATGGCC TTTGCAGGGC TGGCAAGCCA CGTTTGGTGG TGGCGACCAT CCTCCAAAAT CGGATGAAAA CCTGTATTTT CAGGGCATGA GGCGGTCCCC
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 901 CCCGTAGCTC CATATTGGAC ATCCCCAGAA AAGATGGAAA AGAAATTGCA TGCAGTGCCG GCTGCCAAGA CAGTGAAGTT CAAATGCCCT TCCAGTGGGA
1001 CCCCAAACCC CACACTGCGC TGGTTGAAAA ATGGCAAAGA ATTCAAACCT GACCACAGAA TTGGAGGCTA CAAGGTCCGT TATGCCACCT GGAGCATCAT
1101 AATGGACTCT GTGGTGCCCT CTGACAAGGG CAACTACACC TGCATTGTGG AGAATGAGTA CGGCAGCATC AACCACACAT ACCAGCTGGA TGTCGTGGAG
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2001 GGGAAATGTG CGCGGAACCC CTATTTGTTT ATTTTTCTAA ATACATTCAA ATATGTATCC GCTCATGAGA CAATAACCCT GATAAATGCT TCAATAATAT
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```

Figure 4 Cont.

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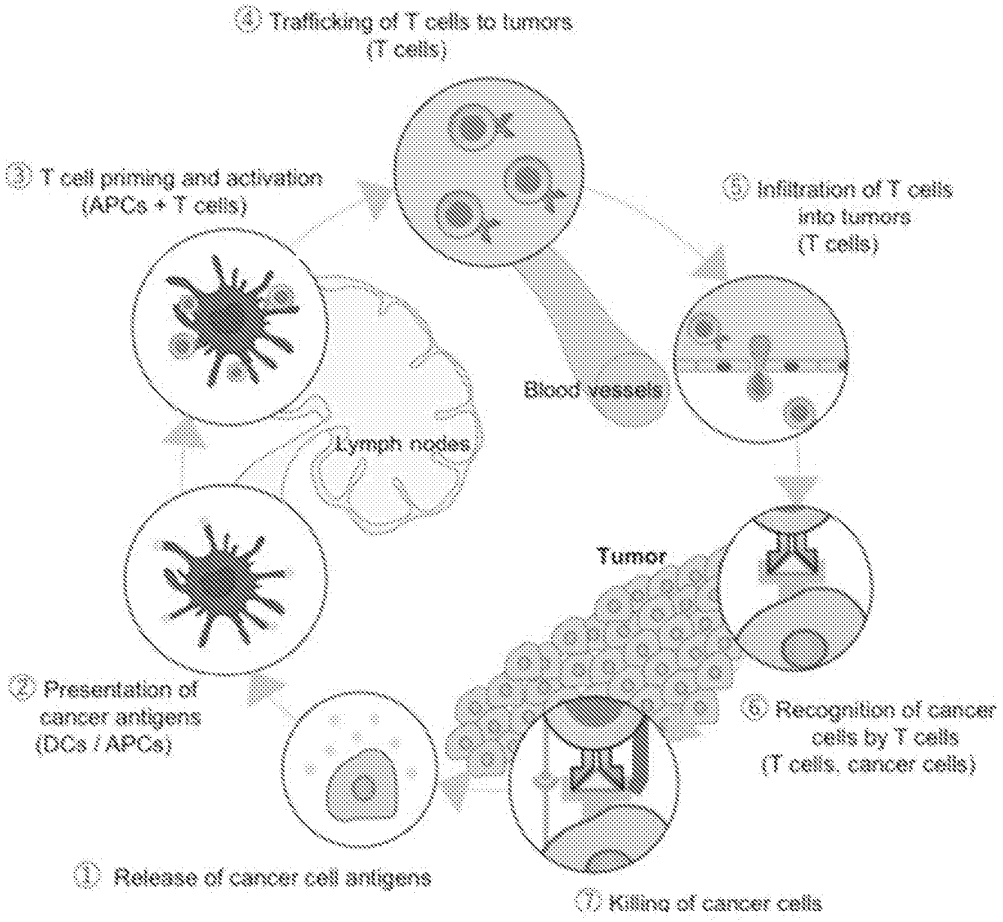

④ Trafficking of T cells to tumors
(T cells)
③ T cell priming and activation
(APCs + T cells)
⑤ Infiltration of T cells
into tumors
(T cells)
Blood vessels
Lymph nodes
Tumor
② Presentation of
cancer antigens
(DCs / APCs)
⑥ Recognition of cancer
cells by T cells
(T cells, cancer cells)
① Release of cancer cell antigens
⑦ Killing of cancer cells

FIGURE 5

Figure 6A Figure 6B Figure 6C Figure 6D