STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

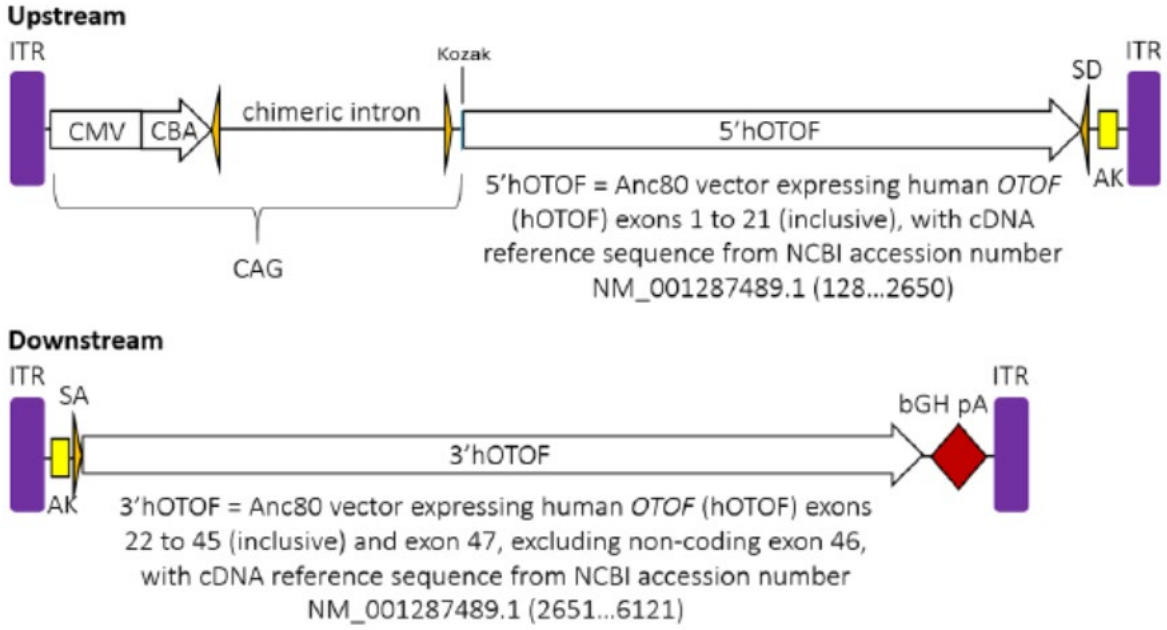
USAN (OP-65)	MELUROTOGENE PARVEC
PRONUNCIATION	mel'' ue roe' toe jeen par' vek
THERAPEUTIC CLAIM	Treatment of OTOF-related congenital hearing loss

DESCRIPTION

DNA (adeno-associated virus vector AAVAnc80-hOTOF cytomegalovirus early enhancer plus chicken β-actin gene promoter plus chimeric intron plus Kozak sequence plus human otoferlin gene OTOF 5′-fragment plus synthetic splice donor site plus adeno-associated virus 2 inverted terminal repeat flanks-specifying), mixt. with DNA (adeno-associated virus vector AAVAnc80-hOTOF synthetic splice acceptor site plus human otoferlin gene OTOF 3′-fragment plus bovine somatotropin gene polyadenylation signal plus adeno-associated virus 2 inverted terminal repeat flanks-specifying) (1:1) (ACI)

SCHEMATIC

Schematic Representation of AAVAnc80-hOTOF Component Vectors



Abbreviations: AK = recombinogenic sequence; bGH = bovine growth hormone; CAG = the cytomegalovirus (CMV) early enhancer element, the promoter and the first exon of the chicken beta actin (CBA) gene, and a chimeric intron composed of the splice donor (SD) and the first intron of CBA and the splice acceptor (SA) sequence derived from the rabbit beta globin gene which together are commonly referred to as the CAG promoter; ITR = inverted terminal repeat; OTOF = human otoferlin gene; pA = polyadenylation signal; SA = splice acceptor; SD = splice donor.

Table 1: Functions of Components in the Upstream AAVAnc80-hOTOF Component Vector (AAVAnc80-5′hOTOF)

	Feature	Nucleotide Position (Size)	Function	NCBI Reference
AAVAnc80-5′hOTOF	ITR	1…145 (145)	Packaging signal	AAV2 / AF043303.1
	CMV enhancer	168…548 (381)	Regulatory element	CMV / K03104.1
	chicken beta-actin promoter	549…825 (277)	Regulatory element	Chicken / X00182.1 [a]
	Chimeric intron	826…1838 (1013)	Regulatory element	Chicken / X00182.1 and rabbit / V00882.1
	Kozak sequence	1872…1881 (10)	Regulatory element	N/A [b]
	5′OTOF	1878…4400 (2523)	OTOF exon 1 to 21	Human / NM_001287489.2
	SD (chimeric intron)	4401…4482 (82)	Regulatory element	NCBI U47120.2
	AK	4483…4559 (77)	Recombinogenic region	E.coli / CP014272.1
	ITR	4598…4742 (145)	Packaging signal	AAV2 / AF043303.1

Abbreviations: N/A = Not applicable; NCBI = National Center for Biotechnology Information.

[a] There is one nucleotide (“G”) included at the start of the CBA promoter sequence that does not appear in the NCBI reference.

[b] Not applicable. The Kozak sequence is taken from Kozak, 1989 and is not included in NCBI.

The components shown in this table add to 4653 base pairs (bp), while the 5′OTOF reference sequence adds to 4742 bp. These 89 bp are composed of multiple cloning sites and are as described: a) 22 bp cloning site between the ITR and CMV enhancer; b) 33 bp cloning site between the chimeric intron and Kozak sequence (with 4 bp overlap between the Kozak and 5′OTOF sequence); and c) 38 bp cloning site between the AK and ITR.

Table 2: Functions of Components in the Downstream AAVAnc80-hOTOF Component Vector (AAVAnc80-3′hOTOF)

AAVAnc80-3′hOTOF	Feature	Nucleotide Position (Size)	Function	NCBI Reference

	ITR	1…145 (145)	Packaging signal	AAV2 / AF043303.1
	AK	168…244 (77)	Recombinogenic region	E.coli / CP014272.1
	SA (chimeric intron)	245…295 (51)	Regulatory element	NCBI U47120.2
	3′OTOF	296…3763 (3468)	OTOF exon 22 through 45 (inclusive) and exon 47, excluding non-coding exon 46	Human / NM_001287489.2
	bGH poly(A) signal	3788…4012 (225)	Termination signal	Cow / M57764.1
	ITR	4051…4195 (145)	Packaging signal	AAV2 / AF043303.1

Abbreviations: N/A = Not applicable; NCBI = National Center for Biotechnology Information.

The components shown in this table add up to 4111 base pairs (bp), while the 3′OTOF reference sequence adds to 4195 bp. These 84 bp are composed of multiple cloning sites: a) 22 bp cloning site between the ITR and AK sequence; b) 24 bp cloning site between the 3′OTOF and bGH polyA signal; and c) 38 bp cloning site between the bGH polyA signal and ITR.

Sequence:

Underline indicates inverted terminal repeat (ITR) sequences, bold indicates CAG promoter region, plain uppercase indicates *OTOF* coding sequences, dashed underline indicates SD and SA chimeric introns in the 5′hOTOF and 3′hOTOF respectively, italics indicate AK recombinogenic sequences, double underline indicates bGH-poly(A) signal, and lowercase indicates multiple cloning sites. Brackets indicate base pair numbering, starting from the beginning of the sequence, including the ITRs and promoter.

5′hOTOF (Upstream portion of *OTOF*):

TTGGCCACTCCCTCTCTGCGCGCTCGCTCGCTCACTGAGGCCGCCCGGGC [50]

AAAGCCCGGGCGTCGGGCGACCTTTGGTCGCCCGGCCTCAGTGAGCGAGC [100]

GAGCGCGCAGAGAGGGAGTGGCCAACTCCATCACTAGGGGTTCCTttgtc [150]

gacgcggccgcacgcgt**GACATTGATTATTGACTAGTTATTAATAGTAAT** [200]

CAATTACGGGGTCATTAGTTCATAGCCCATATATGGAGTTCCGCGTTACA [250]

TAACTTACGGTAAATGGCCCGCCTGGCTGACCGCCCAACGACCCCCGCCC [300]

ATTGACGTCAATAATGACGTATGTTCCCATAGTAACGCCAATAGGGACTT [350]

TCCATTGACGTCAATGGGTGGACTATTTACGGTAAACTGCCCACTTGGCA [400]

GTACATCAAGTGTATCATATGCCAAGTACGCCCCCTATTGACGTCAATGA [450]

CGGTAAATGGCCCGCCTGGCATTATGCCCAGTACATGACCTTATGGGACT [500]

TTCCTACTTGGCAGTACATCTACGTATTAGTCATCGCTATTACCATGGGT [550]

CGAGGTGAGCCCCACGTTCTGCTTCACTCTCCCCATCTCCCCCCCCTCCC [600]

CACCCCCAATTTTGTATTTATTTATTTTTTAATTATTTTGTGCAGCGATG [650]

GGGGCGGGGGGGGGGGGGCGCGCGCCAGGCGGGGCGGGGCGGGGCGAGG [700]

GGCGGGGCGGGGCGAGGCGGAGAGGTGCGGCGGCAGCCAATCAGAGCGGC [750]

GCGCTCCGAAAGTTTCCTTTTATGGCGAGGCGGCGGCGGCGGCGGCCCTA [800]

TAAAAAGCGAAGCGCGCGGCGGGCGGGAGTCGCTGCGTTGCCTTCGCCCC [850]

GTGCCCCGCTCCGCGCCGCCTCGCGCCGCCCGCCCCGGCTCTGACTGACC [900]

GCGTTACTCCCACAGGTGAGCGGGCGGGACGGCCCTTCTCCTCCGGGCTG [950]

TAATTAGCGCTTGGTTTAATGACGGCTCGTTTCTTTTCTGTGGCTGCGTG [1000]

AAAGCCTTAAAGGGCTCCGGGAGGGCCCTTTGTGCGGGGGGGAGCGGCTC [1050]

GGGGGGTGCGTGCGTGTGTGTGTGCGTGGGGAGCGCCGCGTGCGGCCCGC [1100]

GCTGCCCGGCGGCTGTGAGCGCTGCGGGCGCGGCGCGGGGCTTTGTGCGC [1150]

TCCGCGTGTGCGCGAGGGGAGCGCGGCCGGGGGCGGTGCCCCGCGGTGCG [1200]

GGGGGGCTGCGAGGGGAACAAAGGCTGCGTGCGGGGTGTGTGCGTGGGGG [1250]

GGTGAGCAGGGGGTGTGGGCGCGGCGGTCGGGCTGTAACCCCCCCCCTGCA [1300]

CCCCCCTCCCCGAGTTGCTGAGCACGGCCCGGCTTCGGGTGCGGGGCTCC [1350]

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GTGGGGGTGCCGGGCGGGGCGGGGCCGCCTCGGGCCGGGGAGGGCTCGGG [1450]

GGAGGGGCGCGGCGGCCCCCGGAGCGCCGGCGGCTGTCGAGGCGCGGCGA [1500]

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CCTTTGTCCCAAATCTGTGCGGAGCCGAAATCTGGGAGGCGCCGCCGCAC [1600]

CCCCTCTAGCGGGCGCGGGGCGAAGCGGTGCGGCGCCGGCAGGAAGGAAA [1650]

TGGGCGGGGAGGGCCTTCGTGCGTCGCCGCGCCGCCGTCCCCTTCTCCCT [1700]

CTCCAGCCTCGGGGCTGTCCGCGGGGGGACGGCTGCCTTCGGGGGGGACG [1750]

GGGCAGGGCGGGGTTCGGCTTCTGGCGTGTGACCGGCGGCTCTAGAGCCT [1800]

CTGCTAACCATGTTCATGCCTTCTTCTTTTTCCTACAGctcctgggcaac [1850]

gtgctggttattgtgaccggtgccacc [1877]

ATGGCCTTGCTCATCCACCTCAAGACAGTCTCGGAGCTGCGGGGCAGGGG [1927]

CGACCGGATCGCCAAAGTGACTTTCCGAGGGCAATCCTTCTACTCTCGGG [1977]

TCCTGGAGAACTGTGAGGATGTGGCTGACTTTGATGAGACATTTCGGTGG [2027]

CCGGTGGCCAGCAGCATCGACAGAAATGAGATGCTGGAGATTCAGGTTTT [2077]

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ATTGATGACAACAATGCTATCATCAAGACCAGCCTGTGCGTGGAGGTCCG [2227]

GTATCAGGCCACTGACGGCACAGTGGGCTCCTGGGACGATGGGGACTTCC [2277]

TGGGAGATGAGTCTCTTCAAGAGGAAGAGAAGGACAGCCAAGAGACGGAT [2327]

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TGGGCTCCTTCAAAATGGACGTGGGAACCGTGTACTCGCAGCCAGAGCAC [2927]

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ACAACATCAAGACGCCCCACAAGGCCAATGAGACCGACGAAGATGACATT [3077]

GAGGGGAACTTGCTGCTCCCCGAGGGGGTGCCCCCCGAACGCCAGTGGGC [3127]

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CAAGCCTCATGGCCAATGTAAAGAAGGCTTTCATCGGTGAAAACAAGGAC [3227]

CTCGTGGACCCCTACGTGCAAGTCTTCTTTGCTGGCCAGAAGGGCAAGAC [3277]

TTCAGTGCAGAAGAGCAGCTATGAGCCCCTGTGGAATGAGCAGGTCGTCT [3327]

TTACAGACCTCTTCCCCCCACTCTGCAAACGCATGAAGGTGCAGATCCGA [3377]

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GAGCATCAGGACCTGAACGAGGGCCTGGGGGAGGGTGTGTCCTTCCGGGC [3577]

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CAGCGGCCTCGGCCCCGGAAGGAGCCGGGGGATGAGGAAGAAGTAGACCT [3877]

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ACGGAGAAGTCCTACCCTGAGCGTCGCCTGCGGGGCGTCCTGGAGGAGCT [4177]

GAGCTGTGGCTGCTGCCGCTTCCTCTCCCTCGCTGACAAGGACCAGGGCC [4227]

ACTCATCCCGCACCAGGCTTGACCGGGAGCGCCTCAAGTCCTGCATGAGG [4277]

GAGCTGGAAAACATGGGGCAGCAGGCCAGGATGCTGCGGGCCCAGGTGAA [4327]

GCGGCACACGGTGCGGGACAAGCTGAGGCTGTGCCAGAACTTCCTGCAGA [4377]

AGCTGCGCTTCCTGGCGGACGAGGTAAGTATCAAGGTTACAAGACAGGTT [4427]

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CCTCTCTGCGCGCTCGCTCGCTCACTGAGGCCGGGCGACCAAAGGTCGCC [4677]

CGACGCCCGGGCTTTGCCCGGGCGGCCTCAGTGAGCGAGCGAGCGCGCAG [4727]

AGAGGGAGTGGCCAA [4742]

3′hOTOF (Downstream portion of *OTOF)*:

TTGGCCACTCCCTCTCTGCGCGCTCGCTCGCTCACTGAGGCCGCCCGGGC [50]

AAAGCCCGGGCGTCGGGCGACCTTTGGTCGCCCGGCCTCAGTGAGCGAGC [100]

GAGCGCGCAGAGAGGGAGTGGCCAACTCCATCACTAGGGGTTCCTttgtc [150]

gacgcggccgcacgcgt*GGGATTTTGCCGATTTCGGCCTATTGGTTAAAA* [200]

*AATGAGCTGATTTAACAAAAATTTAACGCGAATTTTAACAAAAT*GATAGG [250]

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GCACAGCATTCCCGACATCTTCATCTGGATGATGAGCAACAACAAGCGTG [350]

TCGCCTATGCCCGTGTGCCCTCCAAGGACCTGCTCTTCTCCATCGTGGAG [400]

GAGGAGACTGGCAAGGACTGCGCCAAGGTCAAGACGCTCTTCCTTAAGCT [450]

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GGTGGTCTTGGAGGACGACGACTTCTTCACAGGGGAGAAGTCCAGTGACA [3050]

TCTTCGTGAGGGGGTGGCTGAAGGGCCAGCAGGAGGACAAGCAGGACACA [3100]

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GGCCCGCAATGAGAACGATGAGTTTGAGCTCACGGGCAAGGTGGAGGCTG [3500]

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GCTCCTTGGGGCAtgaactagtgctgatcagcctcgaCTGTGCCTTCTAG [3800]

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AGGAACCCCTAGTGATGGAGTTGGCCACTCCCTCTCTGCGCGCTCGCTCG [4100]

CTCACTGAGGCCGGGCGACCAAAGGTCGCCCGACGCCCGGGCTTTGCCCG [4150]

GGCGGCCTCAGTGAGCGAGCGAGCGCGCAGAGAGGGAGTGGCCAA [4195]

TRADEMARK	None
SPONSOR	Eli Lilly and Company
CODE DESIGNATIONS	AK-OTOF; LY-888891
CAS REGISTRY NUMBER	3091537-98-0
UNII	V8T6PJ54CV
WHO NUMBER	14318

ABC