

Attachment B-1
Summary of AED Treatments

Compound	Approval Dates		Branded Name	Notes	Company	Approved Indications
	Branded	Generic				
Phenytoin	1/6/1953	9/25/1992	Dilantin	[A]	Pfizer	<ul style="list-style-type: none"> - Control of generalized tonic-clonic (grand mal) and complex partial (psychomotor, temporal lobe) seizures - Prevention and treatment of seizures occurring during or following neurosurgery
Carbamazepine	3/11/1968	8/14/1986	Tegretol	[B]	Novartis	<ul style="list-style-type: none"> - Anticonvulsant - Treatment of pain associated with true trigeminal neuralgia
			Tegretol-XR	[C]	Novartis	<ul style="list-style-type: none"> - Anticonvulsant - Treatment of pain associated with true trigeminal neuralgia
Valproates	3/10/1983	2/28/1986	Depakote	[D]	AbbVie	<ul style="list-style-type: none"> - Treatment of manic episodes associated with bipolar disorder - Monotherapy and adjunctive therapy in treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizures - Prophylaxis of migraine headaches
			Depakote ER	[E]	AbbVie	<ul style="list-style-type: none"> - Treatment of acute manic or mixed episodes associated with bipolar disorder - prophylaxis of migraine headaches in adults - Monotherapy and adjunctive therapy in treatment of adults and children 10 years of age or older with complex partial seizures that occur either in isolation or in association with other types of seizures
Gabapentin	12/30/1993	9/12/2003	Neurontin	[F]	Pfizer	<ul style="list-style-type: none"> - Management of postherpetic neuralgia in adults - Adjunctive therapy in treatment of partial seizures with and without secondary generalization in patients over 12 years of age with epilepsy - Adjunctive therapy in treatment of partial seizures in pediatric patients age 3–12 years
Lamotrigine	12/27/1994	6/21/2006	Lamictal	[G]	GlaxoSmithKline	<ul style="list-style-type: none"> - Adjunctive epilepsy therapy in patients at least 2 years of age for partial seizures, primary generalized tonic-clonic seizures, and generalized seizures of Lennox-Gastaut syndrome - Epilepsy monotherapy in patients at least 16 years of age - Bipolar disorder in patients at least 18 years of age
			Lamictal XR	[H]	GlaxoSmithKline	<ul style="list-style-type: none"> - Adjunctive therapy for primary generalized tonic-clonic (PGTC) seizures and partial onset seizures with or without secondary generalization in patients at least 13 years of age - Conversion to monotherapy in patients at least 13 years of age with partial seizures who are receiving treatment with a single AED
Topiramate	12/24/1996	3/27/2009	Topamax	[I]	Janssen	<ul style="list-style-type: none"> - Initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures - Adjunctive therapy for adults and pediatric patients ages 2–16 years with partial onset seizures, or primary generalized tonic-clonic seizures, and in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome - For adults for prophylaxis of migraine headache
			Trokendi XR	[J]	Supernus	<ul style="list-style-type: none"> - Partial onset seizure and primary generalized tonic-clonic seizures - Lennox-Gastaut Syndrome
			Qudexy XR	[K]	Upsher	<ul style="list-style-type: none"> - Partial onset seizures and primary generalized tonic-clonic seizures initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures - Adjunctive therapy in patients 2 years of age and older with partial onset or primary generalized tonic-clonic seizures - Lennox-Gastaut Syndrome adjunctive therapy in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome
Levetiracetam	11/30/1999	11/4/2008	Keppra	[L]	UCB	<ul style="list-style-type: none"> - Adjunctive therapy in treatment of partial onset seizures in adults and children 4 years of age and older with epilepsy - Adjunctive therapy in treatment of myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy - Adjunctive therapy in treatment of primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy
			Keppra XR	[M]	UCB	<ul style="list-style-type: none"> - Adjunctive therapy in treatment of partial onset seizures in patients at least 16 years of age with epilepsy

Compound	Approval Dates		Branded Name	Notes	Company	Approved Indications
	Branded	Generic				
Oxcarbazepine	1/14/2000	10/9/2007	Trileptal	[N]	Novartis	- Monotherapy or adjunctive therapy in treatment of partial seizures in adults - Monotherapy in treatment of partial seizures in children aged 4 years and above with epilepsy - Adjunctive therapy in children aged 2 years and above with epilepsy
Zonisamide	3/27/2000	12/22/2005	Zonegran	[O]	Eisai	- Adjunctive therapy in treatment of partial seizures in adults with epilepsy - Management of neuropathic pain associated with diabetic peripheral neuropathy
Pregabalin	12/30/2004	7/3/2012	Lyrica	[P]	Pfizer	- Management of postherpetic neuralgia - Adjunctive therapy for adult patients with partial onset seizures - Management of fibromyalgia - Management of neuropathic pain associated with spinal cord injury
Lacosamide	10/28/2008	-	Vimpat	[Q]	UCB	- Monotherapy or adjunctive therapy in patients with partial onset seizures - Injection is indicated as short term replacement when oral administration is not feasible
Rufinamide	11/14/2008	-	Banzel	[R]	Eisai	- Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children 4 years and older and adults
Vigabatrin	8/21/2009	-	Sabril	[S]	Lundbeck	- Refractory complex partial seizures in adults as adjunctive therapy in patients who have responded inadequately to several alternative treatments
Ezogabine	6/10/2011	-	Potiga	[T]	GlaxoSmithKline	- Adjunctive treatment of partial-onset seizures in patients aged 18 years and older
Perampanel	10/22/2012	-	Fycompa	[U]	Eisai	- Adjunctive therapy for treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older
Esllicarbazepine acetate	11/8/2013	-	Aptiom	[V]	Sunovion	- Adjunctive treatment of partial-onset seizures

References and sources:

- 2132: Vellturo Declaration, ¶ 14.
- Ex. 1194: Pfizer Website, Dilantin Label, <http://labeling.pfizer.com/showlabeling.aspx?id=544>.
- Ex. 1195: FDA Website, Tegretol Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/016608s098lbl.pdf.
- Ex. 1195: FDA Website, Tegretol Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/016608s098lbl.pdf.
- Ex. 1196: FDA Website, Depakote Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/018723s039lbl.pdf.
- Ex. 1197: FDA Website, Depakote ER Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/18081s44,18082s27,18723s33,19680s22,20593s15,21168s14lbl.pdf.
- Ex. 1198: FDA Website, Neurontin Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020235s043lbl.pdf.
- Ex. 1199: FDA Website, Lamictal Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022251,020764s029,020241s036lbl.pdf.
- Ex. 1200: FDA Website, Lamictal XR Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022115s006lbl.pdf.
- Ex. 1201: FDA Website, Topamax Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020505s038s039,020844s032s034lbl.pdf.
- Ex. 1202: Trokendi XR Website, Trokendi XR Label, <http://www.trokendixr.com/hcp/pdfs/trokendi-prescribing-information.pdf>.
- Ex. 1203: FDA Website, Qudexy XR Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205122s000lbl.pdf.
- Ex. 1204: FDA Website, Keppra Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021035s078s080,021505s021s024lbl.pdf.
- Ex. 1205: FDA Website, Keppra XR Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022285s001lbl.pdf.
- Ex. 1206: FDA Website, Trileptal Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021014s026,021285s021lbl.pdf.
- Ex. 1207: FDA Website, Zonegran Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020789s022s025lbl.pdf.
- Ex. 1208: Pfizer Website, Lyrica Label, <http://labeling.pfizer.com/ShowLabeling.aspx?id=561#section-1>.
- Ex. 1166: Vimpat (lacosamide) Label, 10/28/2008.
- Ex. 1167: Vimpat (lacosamide) Label, 8/29/2014.
- Ex. 1209: FDA Website, Banzel label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021911s005lbl.pdf.
- Ex. 1210: FDA Website, Sabril Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020427s000lbl.pdf.
- Ex. 1211: FDA Website, Potiga Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022345s000lbl.pdf.
- Ex. 1212: FDA Website, Fycompa Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202834lbl.pdf.
- Ex. 1213: U.S. National Library of Medicine Website, Aptiom Label, <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3d0c9554-eaeb-4694-8089-00133fcadce3>.

Attachment B-2

Vimpat Net Sales and TRx in the United States

Year	Net Sales	TRx
2009	\$ 41.5	83,618
2010	\$ 126.1	311,984
2011	\$ 217.9	502,258
2012	\$ 315.9	659,595
2013	\$ 407.0	819,692
2014	\$ 443.5	972,567
2015	\$ 568.3	171,842
2016	\$ 321.1	N/A
Total	\$ 2,441.3	3,521,556

Notes and sources:

Figures are in millions of \$U.S.

Net sales are from Ex. 2174: Vimpat Sales Data, at 2.

Net sales data are from May 2009 to June 2016.

Rx figures are from Ex. 2136: AED Market Basket, at 2.

2015 TRx figures include only January - February.

Attachment B-3

Present Value of Vimpat Sales To Date

Description	Notes	2009	2010	2011	2012	2013	2014	2015	2016
Vimpat net sales	[A]	\$ 41.5	\$ 126.1	\$ 217.9	\$ 315.9	\$ 407.0	\$ 443.5	\$ 568.3	\$ 321.1
Gross margin	[B]	85%	85%	85%	85%	85%	85%	85%	85%
Gross profit	[C]	\$ 35.3	\$ 107.2	\$ 185.2	\$ 268.5	\$ 346.0	\$ 377.0	\$ 483.1	\$ 272.9
Operating margin	[D]	75%	75%	75%	75%	75%	75%	75%	75%
Operating profit	[E]	\$ 31.1	\$ 94.6	\$ 163.4	\$ 236.9	\$ 305.3	\$ 332.6	\$ 426.2	\$ 240.8
Present value factor	[F]	0.970	0.896	0.811	0.734	0.664	0.601	0.544	0.505
Present value	[G]	\$ 30.2	\$ 84.7	\$ 132.5	\$ 173.8	\$ 202.7	\$ 199.9	\$ 231.8	\$ 121.5
Cumulative total present value	[H]	\$ 30.2	\$ 115.0	\$ 247.5	\$ 421.3	\$ 624.0	\$ 823.9	\$ 1,055.6	\$ 1,177.1

Notes and sources:

Figures are in millions of \$U.S.

[A] Attachment B-2.

Net sales data are from May 2009 to June 2016.

[B] Gross margin estimated to be 85% of net sales.

[C] = [A] x [B].

[D] Operating margin estimated to be 75% of net sales.

[E] = [A] x [D].

[F] Present value factors use mid-period convention, discounting to Vimpat launch on 5/26/2009.

2009 present value factor as of 9/12/2009 midway between Vimpat launch on 5/26/2009 and the end of the year.

Calculated using discount factor of 10.5%, consistent with academic literature (though a rate could reasonably be even higher).

2016 Q2 present value factor as of 3/31/2016, midway between 12/31/2015 and 6/30/2016.

[G] = [E] x [F].

[H] = Cumulative sum of [G].

Parameters:

Discount factor for net present value

10.5%

Net present value date (Vimpat launch)

5/26/2009

Attachment C-1

ED U.S. Prescriptions Associated with Epilepsy Indications from Vellturo Declaration

UCB-Defined AED Products	Branded / Generic	Compound	2007 Apr-Dec	2008	2009	2010	2011	2012	2013	2014	2015 Jan-Feb
Aptiom	Branded	Eslicarbazepine acetate	-	-	-	-	-	-	-	15,256	6,728
Banzel	Branded	Rufinamide	-	-	39,144	68,765	82,660	86,421	94,994	101,361	16,888
Depakote	Branded	Valproates	2,470,031	2,395,637	448,952	269,653	223,037	175,856	154,325	135,254	19,621
	Generic	Valproates	205,136	694,528	1,725,242	1,831,481	1,844,192	1,856,602	1,943,080	2,012,149	321,835
Depakote-ER	Branded	Valproates	1,623,762	2,206,333	702,096	293,430	194,348	129,523	109,024	105,535	15,581
	Generic	Valproates	-	1,138	731,946	940,794	984,487	1,005,827	1,046,793	1,052,987	167,848
Dilantin	Branded	Phenytoin	1,324,361	1,537,122	1,336,084	1,174,912	1,021,795	889,813	652,827	552,610	81,329
	Generic	Phenytoin	2,909,752	3,737,603	3,550,487	3,370,705	3,166,627	3,013,269	2,974,633	2,804,935	426,742
Fycompa	Branded	Perampanel	-	-	-	-	-	-	-	19,424	5,442
Keppra-IR	Branded	Levetiracetam	2,749,793	4,074,242	1,121,857	576,284	465,305	368,463	320,220	283,468	41,408
	Generic	Levetiracetam	-	267,524	3,328,124	4,453,067	5,222,054	5,912,051	6,624,941	7,307,462	1,223,661
Keppra-XR	Branded	Levetiracetam	-	14,067	256,602	359,398	331,010	160,311	128,222	111,875	16,894
	Generic	Levetiracetam	-	-	-	-	39,886	198,317	258,302	322,889	57,938
Lamictal	Branded	Lamotrigine	2,373,167	2,479,221	588,461	381,784	312,756	244,612	209,236	178,573	26,189
	Generic	Lamotrigine	19,927	539,815	1,553,933	1,728,706	1,843,963	1,965,404	2,131,576	2,261,356	374,510
Lamictal-XR	Branded	Lamotrigine	-	-	20,380	117,584	170,440	192,617	115,759	87,405	12,356
	Generic	Lamotrigine	-	-	-	-	-	-	128,375	215,518	40,534
Lyrica	Branded	Pregabalin	246,397	391,579	366,580	345,640	341,382	328,105	340,588	357,764	57,893
Neurontin	Branded	Gabapentin	49,981	55,485	49,250	44,028	32,259	24,029	19,436	15,812	2,258
	Generic	Gabapentin	562,477	820,089	940,047	1,082,478	1,226,612	1,422,914	1,619,137	1,871,447	320,143
Potiga	Branded	Ezogabine	-	-	-	-	-	5,387	13,106	7,529	988
Sabril	Branded	Vigabatrin	-	-	2,737	16,342	29,440	22,102	20,149	30,313	2,942
Tegretol	Branded	Carbamazepine	206,490	236,952	206,133	178,669	155,180	121,753	99,858	91,794	13,710
	Generic	Carbamazepine	1,301,915	1,702,783	1,676,449	1,667,926	1,630,542	1,684,848	1,680,420	1,649,924	255,360
Tegretol-XR	Branded	Carbamazepine	562,053	723,866	537,347	335,087	283,718	252,487	233,880	219,630	34,040
	Generic	Carbamazepine	372,682	480,747	613,506	748,133	743,947	748,138	767,258	773,736	123,714
Topamax	Branded	Topiramate	2,354,454	3,237,126	1,192,570	249,746	187,730	147,848	125,112	102,315	13,973
	Generic	Topiramate	-	-	1,071,073	1,636,330	1,722,786	1,841,658	2,041,510	2,204,980	364,584
Trokendi XR	Branded	Topiramate	-	-	-	-	-	-	4,707	50,579	13,117
Trileptal	Branded	Oxcarbazepine	1,411,228	524,118	403,223	257,885	252,302	267,653	153,252	116,092	16,554
	Generic	Oxcarbazepine	145,356	918,225	992,830	1,096,995	1,111,644	1,112,126	1,249,954	1,340,245	221,425
Vimpat - taken as 100%	Branded	Lacosamide	-	-	83,618	311,984	502,258	659,595	819,692	972,567	171,842
Zonegran	Branded	Zonisamide	58,649	64,295	56,735	52,124	46,267	38,817	33,858	30,094	4,433
	Generic	Zonisamide	369,345	514,869	550,185	571,663	596,219	624,816	682,748	741,854	123,920
Topiramate ER	Branded	Topiramate	-	-	-	-	-	-	-	1,105	811
Qudexy XR	Branded	Topiramate	-	-	-	-	-	-	-	82	311
Lamotrigine ODT	Branded	Lamotrigine	-	-	-	-	-	-	-	-	40
Active Pac / Gabapen	Branded	Gabapentin	-	-	-	-	-	-	-	-	0
Total branded			15,430,365	17,940,043	7,411,770	5,033,316	4,631,887	4,115,391	3,648,244	3,586,436	575,348
Total generic			5,886,590	9,677,322	16,733,822	19,128,279	20,132,957	21,385,970	23,148,726	24,559,484	4,022,216
Grand total			21,316,955	27,617,365	24,145,592	24,161,595	24,764,843	25,501,361	26,796,970	28,145,920	4,597,564

Notes and sources:

2136: AED Market Yearly TRx Volume & Market Share - April 2007 – February 2015, at 2.

Note in source indicates, "Factors have been applied to all products with AED indication."
 Impounds per Attachment B-1.

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