

New Drug Fact Blast

Clinical Services

Drug/Manufacturer:	Amvuttra™ (vutrisiran) [Alnylam Pharmaceuticals, Inc.] (am-VOO-trah)
Dosage Formulations:	25 mg/0.5 mL solution for subcutaneous injection, supplied in a single-dose prefilled syringe
FDA Approval Date: FDB File Date:	FDA: June 13, 2022 FDB: June 26, 2022
Indication:	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
Mechanism of Action:	Vutrisiran is a double-stranded small interfering RNA-GalNAc conjugate that causes degradation of mutant and wild-type transthyretin (TTR) mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues.
Dose/Administration:	<ul style="list-style-type: none"> • 25 mg via subcutaneous injection into the abdomen, thigh, or upper arm once every 3 months to be administered by a healthcare professional. • If a dose is missed, administer Amvuttra as soon as possible. Resume dosing every 3 months from the most recently administered dose.
Disease State Clinical Highlights:	<ul style="list-style-type: none"> • Amyloidosis is a general term used to refer to the extracellular tissue deposition of insoluble amyloid fibrils. Deposition of these amyloid fibrils results in a wide range of clinical manifestations depending upon their type, location, and amount. At least 38 different human protein precursors of amyloid fibrils are known. Localized amyloids are found at the site of amyloid formation, while systemic amyloids circulate in the blood and deposit into a variety of tissues and organs. • There are more than 10 forms of systemic amyloidosis, one being transthyretin-mediated amyloidosis (ATTR). TTR is a transport protein that is produced by the liver. When unstable TTR tetramers dissociate, they form misfolded proteins which aggregate into amyloid fibrils and deposit in various organs and tissues. • There are two types of ATTR: hereditary (hATTR) and wild-type (ATTRwt). hATTR is caused by an autosomal-dominant inheritance of a pathogenic <i>TTR</i> gene variant, while ATTRwt occurs in the presence of a normal, wild-type <i>TTR</i> gene. ATTRwt typically occurs with aging, is most often diagnosed in men greater than 65 years of age, and usually manifests with cardiac symptoms. • hATTR can present with a neuropathic phenotype resulting in polyneuropathy (hATTR-PN), a cardiac phenotype resulting in cardiomyopathy (hATTR-CM), or a mixed phenotype where patients experience both cardiomyopathy and polyneuropathy. In hATTR-PN the fibrils deposit in the nervous system causing pain, muscle weakness, and autonomic dysfunction. In hATTR-CM the amyloid fibrils deposit in the myocardium causing cardiomyopathy. • Diagnosis of hATTR is often delayed until significant disease advancement and symptoms typically present in the fifth or sixth decade of life. If left untreated, the average survival after diagnosis for hATTR-PN patients ranges from 5 to 15 years and 2.5 to 4 years for hATTR-CM patients. • Disease prevalence is not well known due to underdiagnosis. There are an estimated 50,000 patients worldwide with some form of hATTR, of which approximately 10,000 present with the neuropathic phenotype. Alnylam estimates there are less than 3,000 patients in the United States currently diagnosed with hATTR-PN.
Drug Clinical Highlights:	<ul style="list-style-type: none"> • Amvuttra is the third medication to be FDA-approved for the treatment of hATTR-PN. <p><u>Warnings/Precautions</u></p> <ul style="list-style-type: none"> • Reduced Serum Vitamin A Levels <ul style="list-style-type: none"> ○ Amvuttra treatment leads to a decrease in serum vitamin A levels. Supplementation at the recommended daily allowance of vitamin A is advised for patients taking

Amvuttra. Patients should be referred to an ophthalmologist if they develop ocular symptoms suggestive of vitamin A deficiency.

Contraindications: none

Pregnancy/Lactation: There are no available data on Amvuttra use in pregnant or lactating women.

Drug Interactions: No clinical drug-drug interaction studies have been performed with Amvuttra. In vitro studies suggest that Amvuttra is not a substrate or inhibitor of cytochrome P450 enzymes and is not expected to cause drug-drug interactions by inducing CYP enzymes or modulating the activities of drug transporters.

Clinical Studies:

- HELIOS-A (N=164) (NCT03759379): randomized, open-label clinical trial in adult patients with hATTR-PN amyloidosis. Patients were randomized to receive 25 mg of Amvuttra subcutaneously once every 3 months (N=122), or 0.3 mg/kg of patisiran intravenously every 3 weeks (N=42) as a reference group. The efficacy of Amvuttra was assessed based on a comparison of the Amvuttra arm of the HELIOS-A study with an external placebo group in the APOLLO (NCT01960348) study, which compared patisiran against placebo in patients with hATTR-PN.
- Key Inclusion Criteria:
 - Aged 18 to 85 years
 - Diagnosis of hATTR amyloidosis with *TTR* pathogenic variant
 - Neuropathy Impairment Score (NIS) between 5 to 130
 - The NIS is a composite clinical scoring system that has been widely used to objectively assess the severity of peripheral neuropathy. The total NIS is graded on a scale of 0 to 244, with a higher score indicating greater impairment.
 - Polyneuropathy Disability (PND) score ≤ IIIB
 - The PND is a scoring system that describes a patient's walking capacity. It consists of four stages: Stage 1 (sensory disturbances without a deficiency in walking capacity), Stage 2 (impaired walking without a need for a stick), Stage 3 (preserved walking with the help of one stick [3A] or two sticks [3B]), and Stage 4 (wheelchair bound or bedridden).
 - Karnofsky Performance Status (KPS) ≥ 60%
 - The KPS is a standardized measure of a patient's ability to perform a variety of ordinary tasks. It is a score that ranges from 0 to 100 with a higher score indicating higher function.
- Key Exclusion Criteria:
 - Prior liver transplant or likely to undergo liver transplant during the study
 - Known other (non-hATTR) forms of amyloidosis or leptomeningeal amyloidosis
 - New York Heart Association heart failure class III or IV
 - Clinically significant liver function test abnormalities
 - Known HIV, HCV, or HBV infection
 - Received prior TTR-lowering treatment
 - Other known causes of neuropathy
- Key Baseline Characteristics:

Characteristic	Amvuttra (HELIOS-A) (N=122)	Placebo (APOLLO) (N=77)
Age, median (range)	60 (26 to 85)	63 (24 to 80)
Males, n (%)	79 (65)	58 (75)
TTR genotype, n (%)		
V30M	54 (44)	40 (52)

Non-V30M	68 (56)	37 (48)
NIS, mean (range)	43 (5 to 127)	57 (7 to 126)
Previous tetramer stabilizer use, n (%)	75 (61.5)	41 (53.2)
PND score, n (%)		
Stage I	44 (36)	20 (26)
Stage II	50 (41)	23 (30)
Stage IIIA	16 (13)	22 (29)
Stage IIIB	12 (10)	11 (14)

- Primary Outcome Measures:
 - Change from baseline to Month 9 in Modified Neuropathy Impairment Score +7 (mNIS+7). The mNIS+7 is an objective assessment of neuropathy and comprises the NIS and Modified +7 composite scores. In the version of the mNIS+7 used in the trial, the NIS objectively measured deficits in cranial nerve function, muscle strength, and reflexes, and the +7 assessed postural blood pressure, quantitative sensory testing, and peripheral nerve electrophysiology. The mNIS+7 has a total score range from 0 to 304 points, with higher scores representing a greater severity of disease.
- Key Secondary Measures:
 - Change from baseline to Month 9 in Norfolk Quality of Life-Diabetic Neuropathy (Norfolk QoL-DN). The Norfolk QoL-DN scale is a patient-reported assessment that evaluates the subjective experience of neuropathy in the following domains: physical functioning/large fiber neuropathy, activities of daily living, symptoms, small fiber neuropathy, and autonomic neuropathy. The Norfolk QoL-DN has a total score range from -4 to 136, with higher scores representing greater impairment.
 - Change from baseline in the Timed 10-Meter Walk Test (10-MWT) at Month 9
 - Change from baseline in the Modified Body Mass Index (mBMI) at Month 9
- Efficacy Results

Endpoint ^a	Baseline, Mean (SD)		Change from Baseline to Month 9, LS Mean (SEM)		Amvuttra-Placebo* Treatment Difference LS Mean (95% CI)	p-value
	Amvuttra N=122 (HELIOS-A)	Placebo* N=77 (APOLLO)	Amvuttra (HELIOS-A)	Placebo* (APOLLO)		
mNIS+7^b	60.6 (36.0)	74.6 (37.0)	-2.2 (1.4)	14.8 (2.0)	-17.0 (-21.8, -12.2)	p<0.001
Norfolk QoL-DN^b	47.1 (26.3)	55.5 (24.3)	-3.3 (1.7)	12.9 (2.2)	-16.2 (-21.7, -10.8)	p<0.001
10-MWT (m/sec)^c	1.01 (0.39)	0.79 (0.32)	0 (0.02)	-0.13 (0.03)	0.13 (0.07, 0.19)	p<0.001
mBMI^d	1058 (234)	990 (214)	7.6 (7.9)	-60.2 (10.1)	67.8 (43.0, 92.6)	p<0.001

CI = confidence interval; LS mean = least squares mean; mBMI = modified body mass index; mNIS = modified Neuropathy Impairment Score; QoL-DN = Quality of Life-Diabetic Neuropathy; SD = standard deviation; SEM = standard error of the mean, 10-MWT = 10 minute walk test

*External placebo group from another randomized controlled trial (NCT01960348)

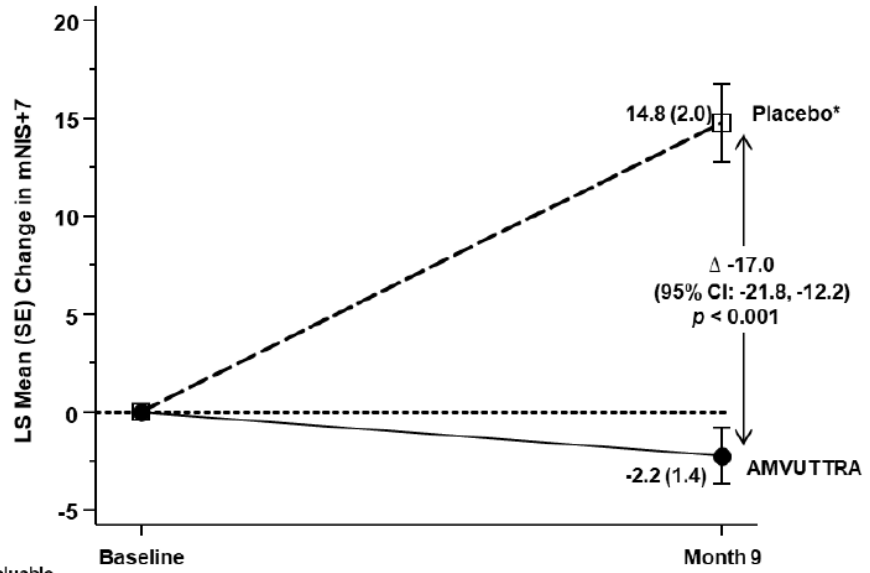
^aAll endpoints analyzed using the analysis of covariance (ANCOVA) with multiple imputation (MI) method

^bA lower number indicates less impairment/fewer symptoms

^cA higher number indicates less disability/less impairment

^dmBMI: nominal p-value; body mass index (BMI; kg/m²) multiplied by serum albumin (g/L)

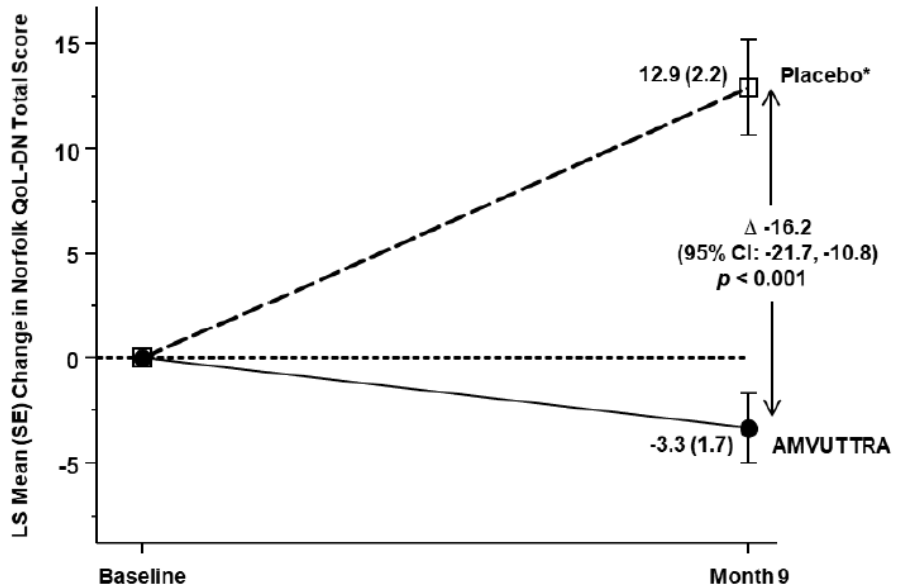
Figure 1: Change from Baseline in mNIS+7
(Comparison of AMVUTTRA Treatment in Study 1 to an External Placebo Control*)



<u>N evaluable</u>	Baseline	Month 9
Placebo	77	67
AMVUTTRA	122	114

A decrease in mNIS+7 indicates improvement
 Δ indicates between-group treatment difference, shown as the LS mean difference (95% CI) for AMVUTTRA – placebo
 *External placebo group from another randomized controlled trial (NCT01960348)

Figure 3: Change from Baseline in Norfolk QoL-DN Total Score
(Comparison of AMVUTTRA Treatment in Study 1 to an External Placebo Control*)



<u>N evaluable</u>	Baseline	Month 9
Placebo	76	65
AMVUTTRA	121	114

A decrease in Norfolk QoL-DN score indicates improvement
 Δ indicates between-group treatment difference, shown as the LS mean difference (95% CI) for AMVUTTRA – placebo
 *External placebo group from another randomized controlled trial (NCT01960348)

	<ul style="list-style-type: none"> Adverse reactions reported in at least 5% of patients treated with Amvuttra: arthralgia (11%), dyspnea (7%), and vitamin A decrease (7%). Two serious adverse reactions of atrioventricular (AV) heart block (1.6%) occurred in patients treated with Amvuttra, including one case of complete AV block. 																																												
Price Per Unit (WAC):	\$115,875.00 per syringe; \$463,500 per year																																												
Therapeutic Alternatives:	<ul style="list-style-type: none"> Prior to the introduction of TTR-lowering agents (Tegsedi[®], Onpattro[®]), symptomatic management and organ transplantation were the sole treatment options for hATTR-PN. Liver transplantation is still a treatment option for hATTR-PN but is only indicated in younger patients without significant disease. Diflunisal is a nonsteroidal anti-inflammatory drug (NSAID) used off-label for the treatment of hATTR-PN. It has been found to stabilize TTR tetramers and delay peripheral neurological impairment compared to placebo; however, it has not been found to reverse existing neurologic impairment as seen with newer treatments. Table 1 below compares the three FDA-approved treatments for hATTR-PN. Tegsedi offers a more convenient route of administration compared to Onpattro, however it has a Risk Evaluation and Mitigation Strategy (REMS) program due to risk of thrombocytopenia and glomerulonephritis and requires frequent laboratory monitoring. <table border="1" data-bbox="488 730 1373 1104"> <caption>Table 1: FDA-Approved hATTR-PN Medications</caption> <thead> <tr> <th>Drug</th> <th>MOA</th> <th>Administration</th> <th>Annual Cost (WAC)</th> </tr> </thead> <tbody> <tr> <td>Onpattro[®] (patisiran) (Alynlam)</td> <td>Gene silencing via siRNA</td> <td>Weight-based IV injection dosed every 3 weeks</td> <td>\$499,035*</td> </tr> <tr> <td>Tegsedi[®] (inotersen) (lonis)</td> <td>Gene silencing via antisense oligonucleotide</td> <td>SC injection dosed once-weekly</td> <td>\$477,193</td> </tr> <tr> <td>Amvuttra[™] (vutrisiran) (Alynlam)</td> <td>Gene silencing via siRNA</td> <td>SC injection dosed every 3 months</td> <td>\$463,500</td> </tr> </tbody> </table> <p>*Based on 80-kg patient</p> <ul style="list-style-type: none"> Though there have been no head-to-head studies comparing the effectiveness of hATTR-PN agents, there are similarities in the study designs such as primary endpoints. Based on the baseline mNIS+7 scores in the Amvuttra trial (HELIOS-A), it appears the patient population had less severe disease. Table 2 below summarizes the efficacy results for Onpattro, Tegsedi, and Amvuttra. <table border="1" data-bbox="448 1289 1533 1734"> <caption>Table 2: Comparative Efficacy of FDA-Approved hATTR-PN Treatments</caption> <thead> <tr> <th></th> <th>Amvuttra</th> <th>Onpattro</th> <th>Tegsedi</th> </tr> </thead> <tbody> <tr> <td>Trial</td> <td>HELIOS-A</td> <td>APOLLO</td> <td>NEURO-TTR</td> </tr> <tr> <td>Baseline mNIS+7 score^{a,b}</td> <td>60.6</td> <td>80.9</td> <td>80.2</td> </tr> <tr> <td>Baseline Norfolk QoL-DN Score^b</td> <td>47.1</td> <td>59.6</td> <td>48.7</td> </tr> <tr> <td>Time of Outcome Evaluation</td> <td>18 months</td> <td>18 months</td> <td>66 weeks</td> </tr> <tr> <td>Change from baseline in mNIS+7 Score^b</td> <td>-0.46</td> <td>-6.0</td> <td>5.8</td> </tr> <tr> <td>Change from Baseline in Norfolk QoL-DN Score^b</td> <td>-1.2</td> <td>-6.7</td> <td>1</td> </tr> </tbody> </table> <p>mNIS+7 = modified neurologic impairment score +7, Norfolk QoL-DN = Norfolk quality of life-diabetic neuropathy ^aThe NEURO-TTR trial defined mNIS+7 score slightly different than the APOLLO and HELIOS trials ^bScores are reflective of the treatment arm</p>	Drug	MOA	Administration	Annual Cost (WAC)	Onpattro [®] (patisiran) (Alynlam)	Gene silencing via siRNA	Weight-based IV injection dosed every 3 weeks	\$499,035*	Tegsedi [®] (inotersen) (lonis)	Gene silencing via antisense oligonucleotide	SC injection dosed once-weekly	\$477,193	Amvuttra [™] (vutrisiran) (Alynlam)	Gene silencing via siRNA	SC injection dosed every 3 months	\$463,500		Amvuttra	Onpattro	Tegsedi	Trial	HELIOS-A	APOLLO	NEURO-TTR	Baseline mNIS+7 score^{a,b}	60.6	80.9	80.2	Baseline Norfolk QoL-DN Score^b	47.1	59.6	48.7	Time of Outcome Evaluation	18 months	18 months	66 weeks	Change from baseline in mNIS+7 Score^b	-0.46	-6.0	5.8	Change from Baseline in Norfolk QoL-DN Score^b	-1.2	-6.7	1
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<p>Prior Authorization Approval Criteria:</p>	<p>Must meet the following criteria:</p> <p><u>Initial Therapy:</u></p> <ul style="list-style-type: none"> • Prescribed by or in consultation with a neurologist or other specialist in the treated disease state AND • Participant is aged 18 years or older AND • Documented diagnosis of polyneuropathy caused by hATTR confirmed by transthyretin genotyping AND • Participant is not concomitantly using a TTR-lowering agent or a TTR-stabilizing agent AND • Quantity limit: 4 injections per year • Initial approval 6 months <p><u>Continuation of Therapy:</u></p> <ul style="list-style-type: none"> • Documented benefit of therapy defined as improvement, stabilization, or slowing of disease progression • Continued approval 1 year <p>Additional Provider Diagnostic/Monitoring Criteria, if desired:</p> <ul style="list-style-type: none"> • Amvuttra has not been studied in patients with severe renal impairment, end-stage renal disease, or moderate to severe hepatic impairment.
<p>Implication to State Medicaid Program:</p>	<ul style="list-style-type: none"> • LOE: est. 2036 • Amvuttra will be a limited distribution drug, available through US Bioservices and Orsini Specialty Pharmacy. • Tafamidis (Vyndamax, Vyndaqel) is a TTR-stabilizing agent currently approved for hATTR-CM. There is limited data evaluating the concomitant use of TTR-stabilizing agents and TTR-lowering agents. Ongoing Phase 3 trials for Onpattro and Amvuttra in patients with hATTR-CM allow enrollment of patients currently receiving tafamidis. • HELIOS-A (NCT03759379) includes an ongoing randomized treatment extension segment compared Amvuttra 25 mg every 3 months against Amvuttra 50 mg every 6 months. Data from this segment is expected in late 2022. • HELIOS-B (NCT04153149) is an ongoing Phase 3 trial evaluating Amvuttra in patients with hATTR-CM. <ul style="list-style-type: none"> ○ Primary endpoints include all-cause mortality and recurrent cardiovascular (CV) events (CV-related hospitalizations or urgent heart failure visits over 30-36 months) ○ Includes participants with hATTR-CM and ATTRwt. ○ Alnylam estimates the additional hATTR-CM indication would make 40,000 more patients eligible for treatment worldwide, while the ATTRwt indication could make an additional 200,000 to 300,000 patients eligible worldwide. ○ Topline results expected in early 2024. • Eplontersen (AstraZeneca/Ionis) <ul style="list-style-type: none"> ○ Pipeline agent currently in Phase 3 trials for both hATTR-PN (NEURO-TTRansform, NCT04136184) and hATTR-CM (CARDIO-TTRansform, NCT04136171). • Acoramidis (BridgeBio/Eidos) <ul style="list-style-type: none"> ○ Pipeline agent currently in Phase 3 trial for hATTR-CM (ATTRIBUTE-CM, NCT03860935). • APOLLO-B (NCT03997383) is an ongoing Phase 3 trial evaluating Onpattro in patients with hATTR-CM

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