Qulipta® (Atogepant)
One Page Summary

INDICATION AND USAGE: Atogepant is indicated for the preventive treatment of migraine in adults.
MECHANISM OF ACTION: Atogepant is a calcitonin gene-related peptide receptor antagonist.
PHARMACODYNAMICS: At a dose 5 times the maximum recommended daily dose, atogepant does not prolong the QT interval to any clinically relevant extent.
PHARMACOKINETICS AND DRUG INTERACTIONS: Following oral administration, atogepant is absorbed with peak plasma concentrations at approximately 1 to 2 hours. Atogepant displays dose-proportional pharmacokinetics within the recommended dose range. Plasma protein binding of atogepant is 95.3% in vitro. Atogepant is eliminated mainly through metabolism, primarily by CYP3A4. The elimination half-life of atogepant is approximately 11 hours. Atogepant is excreted mostly via the fecal route, while the renal route is a minor route of elimination. Dose modifications are recommended when using strong CYP3A4 inhibitors, strong, moderate, and weak CYP3A4 inducers, OATP inhibitors and severe renal impairment or end stage renal disease.
EFFICACY: The efficacy of atogepant for the preventive treatment of migraine was demonstrated in three randomized, double-blind, placebo-controlled trials [Study 1 (NCT03777059), Study 2 (NCT02848326), and Study 3 (NCT03855137]. Study 1 randomized patients to placebo (n =223) or atogepant 10 mg (n = 222) or 30 mg (n = 230) or 60 mg (n =235), Study 2 randomized patients to placebo (n = 92) or atogepant 10 mg (n = 182) or 30 mg (n = 177) or 60 mg (n =178) and Study 3 randomized patients to placebo (n = 259) or atogepant 60 mg (n = 262). In all studies, patients were allowed to use acute headache treatments (i.e., triptans, ergotamine derivatives, NSAIDs, acetaminophen, and opioids) as needed. The use of a concomitant medication that acts on the CGRP pathway was not permitted for either acute or preventive treatment of migraine. The studies excluded patients with myocardial infarction, stroke, or transient ischemic attacks within six months prior to screening. The primary efficacy endpoint for Study 1 and Study 3 was the change from baseline in mean monthly migraine days (MMD) across the 12-week treatment period. The primary efficacy and secondary endpoints for Study 1 and 3 are listed in the tables below.

. Efficacy Endpoints in Study 1

	QULIPTA 10 mg N=214	QULIPTA 30 mg N=223	QULIPTA 60 mg N=222	Placebo N=214
Monthly Migraine Days (MMD) across 12 weeks				
Baseline	7.5	7.9	7.8	7.5
Mean change from baseline	-3.7	-3.9	-4.2	-2.5
Difference from placebo	-1.2	-1.4	-1.7	
p-value	<0.001	<0.001	<0.001	
Monthly Headache Days across 12 weeks				
Baseline	8.4	8.8	9.0	8.4
Mean change from baseline	-3.9	-4.0	-4.2	-2.5
Difference from placebo	-1.4	-1.5	-1.7	
p-value	<0.001	<0.001	<0.001	
Monthly Acute Medication Use Days across 12 weeks				
Baseline	6.6	6.7	6.9	6.5
Mean change from baseline	-3.7	-3.7	-3.9	-2.4
Difference from placebo	-1.3	-1.3	-1.5	
p-value	<0.001	<0.001	<0.001	
≥ 50% MMD Responders across 12 weeks				
% Responders	56	59	61	29
Difference from placebo (%)	27	30	32	
p-value	<0.001	<0.001	<0.001	
MSQ v2.1 RFR Domain* at week 12				
Baseline	44.9	44.0	46.8	46.8
Mean change from baseline	30.4	30.5	31.3	20.5
Difference from placebo	9.9	10.1	10.8	
p-value	<0.001	<0.001	<0.001	
AIM-D PDA Domain across 12 weeks**				
Baseline	15.5	16.9	15.9	15.2
Mean change from baseline	-7.3	-8.6	-9.4	-6.1
Difference from placebo	-1.2	-2.5	-3.3	
p-value	NS†	<0.001	<0.001	
AIM-D PI Domain* across 12 weeks**				
Baseline	11.7	13.0	11.6	11.2
Mean change from baseline	-5.1	-6.0	-6.5	-4.0
Difference from placebo	-1.1	-2.0	-2.5	
p-value	NS†	0.002	<0.001	

. Efficacy Endpoints in Study 3

	QULIPTA 60 mg QD N=256	Placebo N=246
Monthly Migraine Days (MMD) across 12 weeks		
Baseline	19.2	18.9
Mean change from baseline	-6.9	-5.1
Difference from placebo	-1.8	
p-value	<0.001	
Monthly Headache Days across 12 weeks		
Baseline	21.5	21.4
Mean change from baseline	-7.0	-5.1
Difference from placebo	-1.9	
p-value	<0.001	
Monthly Acute Medication Use Days across 12 weeks		
Baseline	15.5	15.4
Mean change from baseline	-6.2	-4.1
Difference from placebo	-2.1	
p-value	<0.001	
≥ 50% MMD Responders across 12 weeks		
% Responders	41	26
Difference from placebo (%)	15	
p-value	<0.001	
MSQ v2.1 RFR Domain* at week 12		
Baseline	43.4	43.9
Mean change from baseline	23.3	17.2
Difference from placebo	6.2	
p-value	<0.001	
AIM-D PDA Domain across 12 weeks**		
Baseline	31.2	29.5
Mean change from baseline	-12.8	-9.4
Difference from placebo	-3.4	
p-value	<0.001	
AIM-D PI Domain* across 12 weeks**		
Baseline	27.1	25.2
Mean change from baseline	-10.6	-7.9
Difference from placebo	-2.7	
p-value	0.003	

* Migraine Specific Quality of Life Questionnaire version 2.1 Role Function-Restrictive domain score
** Activity Impairment in Migraine-Diary Performance of Daily Activities domain score
*** Activity Impairment in Migraine-Diary Physical Impairment domain score

ADVERSE REACTIONS: The most common adverse reactions were nausea (5-9% vs. 3% placebo), constipation (6-8% vs. 2% placebo), fatigue/somnolence (4-5% vs. 4% placebo), decreased appetite (1-3% vs. <1% placebo), and dizziness (2-3% vs 2% placebo).
CONTRAINDICATIONS: Atogepant is contraindicated in patients with a history of hypersensitivity to atogepant or any of the components of the tablet.
SPECIFIC POPULATIONS: There are no adequate data on the developmental risk associated with the use of atogepant in pregnant women. There are no data on the presence of atogepant in human milk, the effects of atogepant on the breastfed infant, or the effects of atogepant on milk production. Safety and effectiveness in pediatric patients have not been established. Population pharmacokinetic modeling suggests no clinically significant pharmacokinetic differences between elderly and younger subjects. Clinical studies of atogepant did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range. No dose adjustment of atogepant is recommended for patients with mild or moderate hepatic impairment. Avoid use of atogepant in patients with severe hepatic impairment. No dose adjustment is recommended for patients with mild or moderate renal impairment. In patients with severe renal impairment (CLcr 15-29 mL/min), and in patients with end-stage renal disease (ESRD) CLcr <15 mL/min), the recommended dosage of atogepant is 10 mg once daily in episodic migraine and avoid use in chronic migraine.
DOSAGE AND ADMINISTRATION: Atogepant may be taken with or without food. The recommended dose of atogepant is 10 mg, 30 mg or 60 mg taken orally once a day for prevention of episodic migraine, and 60 mg taken orally once a day for prevention of chronic migraine.

For further information please consult the accompanying Qulipta full prescribing information.

QULIPTA™ (atogepant) [prescribing information]. Madison, NJ: AbbVie USA, Inc.; April 2023

This one-page summary is sponsored by AbbVie. AGPT-US-00089-FM APPROVED 4-19-23

From: Joey
Sent: Monday, June 26, 2023 6:30:03 PM (UTC-08:00) Pacific Time (US & Canada)
To: Pharmacy Drug Information
Subject: Support for Daybue coverage

Thank you for considering coverage of the new drug Daybue for the treatment of Rett Syndrome. As the Oregon parent representative for the International Rett Syndrome Foundation and a board member of the Northwest Rett Syndrome Association, I represent approximately 200 families that could benefit from the use and coverage of this medication. The majority of individuals who experience this disability are fee for service clients of the Oregon Health Plan so recommended coverage is essential for access to this groundbreaking FDA approved treatment. My daughter participated in the clinical trial and we are hopeful that Daybue will provide some improvement in her symptoms. We know, even with primary and secondary insurance coverage that it would be cost prohibitive and ask you to please add this to the approved medication list for OHP clients. Thank you.

Joey Razzano

Mom to Jade Razzano, who experiences Rett Syndrome