
Migraine Key Catalysts for 2023

abbvie **AMGEN**  **AEON**  **axsome**  **Impel**
PHARMACEUTICALS *Lilly* *Lundbeck*   **NOVARTIS**  **Pfizer** **teva**  **TONIX**
PHARMACEUTICALS vaxxinity 

Trends in Migraine



Increasing CGRP focus

- In the US, 10 new products have been approved since 2018 for acute and preventive migraine, the majority of them (8 of 10) targeting CGRP
- Pfizer's Zavzpret is the latest US approval, the first CGRP receptor antagonist nasal spray



Another neurotoxin

- Aeon's ABP-450 (Ph2 ongoing) could become the second neurotoxin for migraine after AbbVie's Botox®
- Ph2 Toplevel results in episodic migraine expected by 2H'23

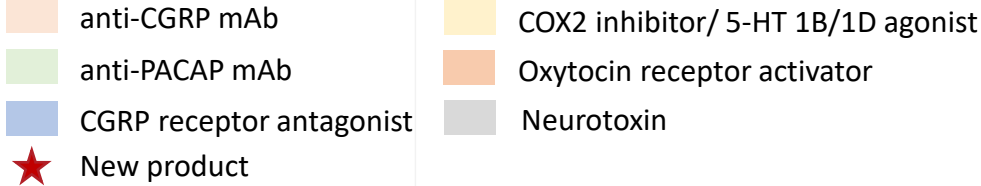


New class in pipeline

- Lundbeck's Lu AG09222 (Ph2 completed), an anti-PACAP mAb, represents a novel alternative to CGRPs-targeting drugs
- PACAP selectively activates the PAC1 receptor
- Targeting a new segment of treatment-resistant migraine patients

Migraine key catalysts for 2023

Zavzpret is the latest major product approval, the first CGRP receptor antagonist nasal spray

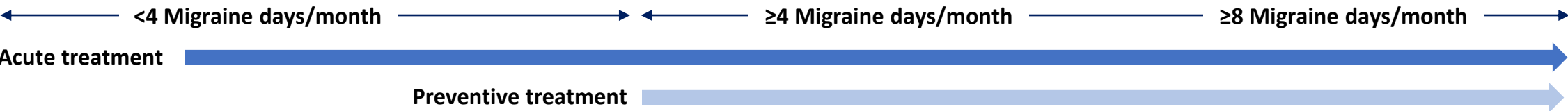
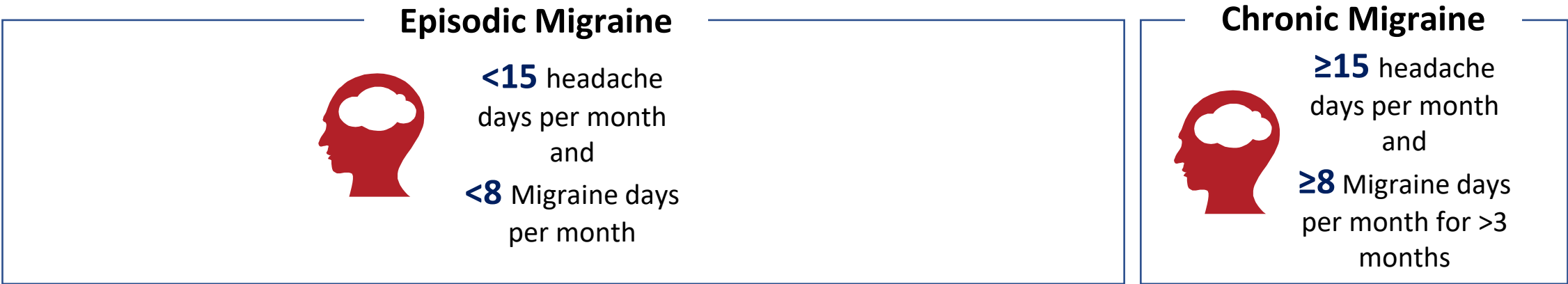
	Q1 2023			Q2 2023			Q3 2023			Q4 2023		
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Key conferences												
Regulatory milestones	 Mar'23 ★ <u>Zavzpret approval</u> (nasal spray for acute migraine)			 Apr'23 <u>Qulipta sNDA Approved</u> (prevention of chronic migraine)		 Mid-23 <u>Zavzpret launch</u> (nasal spray for acute migraine)		 2H'23 <u>AXS-07 NDA resubmission</u> (acute migraine)		 2H'23 <u>Qulipta EMA approval</u> (preventive migraine)		
Data readouts				 Q2'23 <u>UB-313 Ph1 interim results</u> (preventive migraine)						 4Q'23 <u>TNX-1900 Ph2 study</u> - Topline results (Intranasal oxytocin for prevention of chronic migraine)		
				 Apr'23 <u>Lu AG09222 Positive Ph2 PoC results</u> (preventive migraine)			 2H'23 <u>ABP-450 (prabotulinumtoxinA) Ph2 topline results</u> (prevention of episodic migraine)					
Clinical trial initiations	 Mar'23 <u>Qulipta Ph3</u> (Pediatric; PCD=Jul'29)											

Sources: Biomedtracker; Only key US and EU events shown; **Abbreviations:** CGRP: Calcitonin gene-related peptide; PACAP: Pituitary adenylate-cyclase-activating polypeptide; COX: Cyclooxygenase; 5-HT: 5-hydroxytryptamine

Migraine types and pharmacologic treatment approaches

Preventive treatment options are available for patients with ≥ 4 migraine days/month

Depending on the frequency of migraine days & headache days per month, migraine is classified into two categories - Episodic & Chronic^{1,2}



Acute treatment ³ (treating acute Migraine attacks as they arise)	
Mild to moderate attack • NSAIDS, • Analgesics	Moderate to severe attack • Triptans • Ergotamine derivatives • Ditans • Gepants • Neuromodulation devices

Preventive treatment ³ (reducing the frequency of Migraine attacks)	
First Line • Anticonvulsant drugs • Beta-blockers • Angiotensin receptor blockers	Second line • Gepants • Triptans • CGRP monoclonal antibodies • Botox

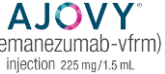
Sources: 1. [American Migraine Foundation](#); 2. [International Headache Society](#); 3. [American Headache Society](#)



Key branded drugs in the US migraine market

10 new products have been approved since May 2018; Nurtec is the only one approved for both indications

Indicates approval in specific indication

Company	Approved Product	RoA	US Approval	MoA	Drug Class	Acute Tx	Preventive Tx
	 (erenumab-aooe) injection 70mg/140mg/mL		May'18	anti-CGRP mAb	CGRP mAb	-	
	 (fremanezumab-vfrm) injection 225 mg/1.5 mL		Sep'18			-	
	 (galcanezumab-gnlm)		Sep'18			-	
	 (eptinezumab-jjmr)		Feb'20			-	
	 (ubrogepant) tablets 150mg		Dec'19	CGRP receptor antagonist	Gepants		-
	 (rimegepant) orally disintegrating tablets 75 mg		Feb'20				Episodic Migraine
	 (atogepant) tablets		Sep'21			-	
	 (zavegepant)		Mar'23				-
	 (dihydroergotamine mesylate) nasal spray 0.725 mg per spray		Sep'21	Serotonin 5-HT1B/D receptor	Ergotamine (DHE)		-
	 onabotulinumtoxinA injection		Oct'10	SNARE protein modulator	Neurotoxin	-	Chronic Migraine
	 (lasmiditan) tablets 50mg, 100mg		Oct'19	Serotonin 5-HT1F receptor agonist	Ditan		-

Note: Other therapies include - **Triptans** (sumatriptan, zolmitriptan, rizatriptan, naratriptan, frovatriptan, almotriptan, eletriptan); Abbreviations: SC: Subcutaneous; IV: Intravenous, IM: Intramuscular



Directional Clarity
Actionable Insights
Exponential Advantage

If you need help developing a
winning strategy, email us at info@atacana.com.



Directional Clarity
Actionable Insights
Exponential Advantage

If you need help developing a
winning strategy, email us at info@atacana.com