



ALKIVIA Study Topline Results

August 17, 2026



Forward-Looking Statements

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An Important Win for the Autoimmune Myositis Community



Patients

Delivering transformative outcomes

FcRn Science

Sixth first-in-class dataset

Rheumatology

First phase 3 data in rheumatology

argenx 

First and Only Positive Results in Multiple Subtypes of Autoimmune Myositis

Today's Results



A win for both IMNM and DM - met primary endpoint on combined population ($p=0.0011$), with early and sustained improvements across primary and secondary endpoints

Consistent benefit across skin and muscle, with comparable magnitude of treatment effect in both subtypes

Safety profile was consistent with prior studies and the known safety profile of efgartigimod

“

For people living with myositis, the goal is straightforward: regain strength and function, and get off long-term steroids. Until now we have had limited targeted therapies to offer patients.”

– Dr. Rohit Aggarwal

Addressing Substantial Unmet Need in Autoimmune Myositis



Persistent muscle weakness
as hallmark symptom

Systemic manifestations beyond skin and
muscle can lead to hospitalization

IMNM patients can become **wheelchair
bound** within 3-6 months

"Time is muscle" – uncontrolled disease
can lead to **irreversible muscle loss**

Significant disease burden leads
to **depression and anxiety**

Pioneering FcRn Biology with VYVGART

Creating the FcRn Roadmap



6 First-in-Class Phase 3 Data Sets

Shaping the Treatment Paradigm

- ✓ Signature efficacy profile: rapid, deep, sustained responses
- ✓ ~25K patient safety years
- ✓ Broadest product presentation, empowering patient choice



Not actual size.

Bringing our Proven Approach to Rheumatology





“

This is an invisible disease. You think you're the only one, but once you start talking to people with similar experiences it's amazing.

Melissa, living with autoimmune myositis

ALKIVIA Phase 2/3 Adaptive Basket Study

PHASE 2 ANALYSIS

Data supported continued enrollment
across subtypes in Phase 3



Trial Features

NO ENROLLMENT TARGET PER SUBTYPE

Enrollment reflects
unmet need, prevalence

ACTIVE MUSCLE WEAKNESS

Despite standard
of care

PRIMARY ANALYSIS*†

Evaluate strength
of evidence by each
subtype

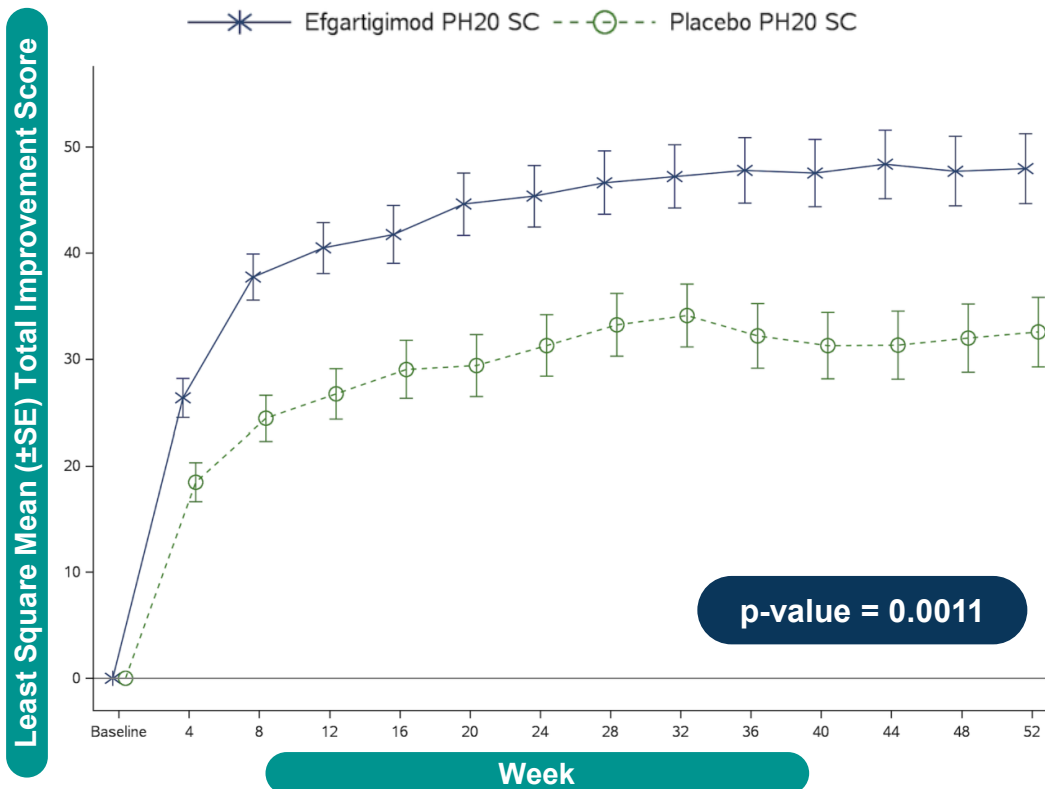
TAPERING PROTOCOL*

Supports real world
demand for steroid
reduction

*Phase 3 only † US

Rapid, Significant and Sustained Response Through 52 Weeks

Mean TIS Improvement in IMNM + DM Through Week 52



Consistent Treatment Effect

- ✓ Consistent across core TIS measures with benefit in both muscle and skin domains
- ✓ Consistent across primary and secondary endpoints
- ✓ Consistent with the VYVGART signature: rapid and sustained response

Consistent Response Across IMNM and DM

Baseline Characteristics

Baseline Characteristics	Efgartigimod		Placebo	
	IMNM (n=46)	DM (n=26)	IMNM (n=46)	DM (n=28)
Age (mean, years)	55.5	51.3	54.1	51.3
Gender				
Female	63.0	69.2	58.7	67.9
Male	37.0	30.8	41.3	32.1
MSA+	95.7%	80.8%	93.5%	78.6%
Medication at Baseline				
• Corticosteroids	89.1%	84.6%	76.1%	85.7%
• Non-steroidal immunosuppressant	67.4%	84.6%	80.4%	89.3%
• Combination	56.5%	69.2%	56.5%	75%
MMT8* (mean)	123.7	118.7	120.6	115.8

Mean TIS Evaluated at 52 Weeks

IMNM + DM Combined Population

Active	Placebo	Delta	p-value
47.95	32.56	15.39	p=0.0011

IMNM

Active	Placebo	Delta	p-value
45.05	30.24	14.81	p=0.0048

DM

Active	Placebo	Delta	p-value
51.51	36.96	14.54	p=0.1093

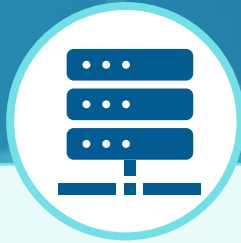
ALKIVIA Phase 3 Safety Profile

	Efgartigimod PH20 SC (N=86; PYFU=75.8)	Placebo PH20 SC (N=89; PYFU=71.7)
	n (%)	n (%)
≥1 AE	80 (93.0)	78 (87.6)
≥1 SAE	18 (20.9)	12 (13.5)
≥1 grade ≥3 AE	23 (26.7)	13 (14.6)
≥1 AE leading to study drug discontinuation	6 (7.0)	12 (13.5)
≥1 AESI (infection)	51 (59.3)	43 (48.3)
≥1 injection site reaction	44 (51.2)	19 (21.3)
≥1 fatal AE	0	0
Most common AEs (occurring in >10% of participants)		
Nasopharyngitis	12 (14.0)	10 (11.2)
Upper respiratory tract infection	8 (9.3)	15 (16.9)
Injection site erythema	22 (25.6)	5 (5.6)
Injection site pain	9 (10.5)	7 (7.9)
Injection site reaction	11 (12.8)	5 (5.6)
IIM worsening	1 (1.2)	13 (14.6)
headache	8 (9.3)	9 (10.1)

Path Forward to Bringing Innovation to Patients



**Moving with urgency
toward regulatory filing**



**Additional data to be
shared at future medical
congress**



**Preparing commercial
organization for launch**

Accelerating Toward Vision 2030 – and Beyond

Vision 2030

50k

patients on
treatment

10

labeled
indications

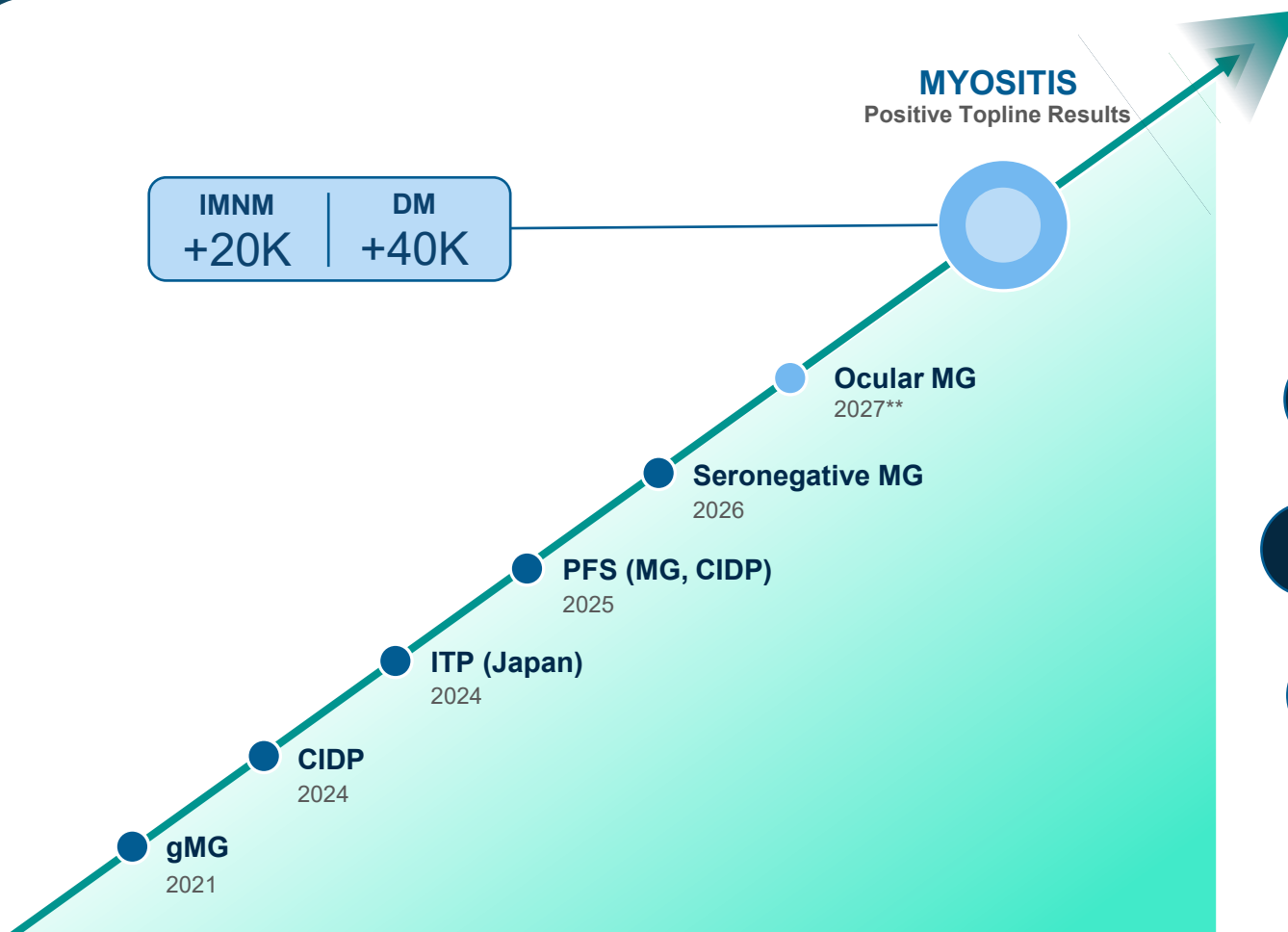
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new molecules
in Phase 3

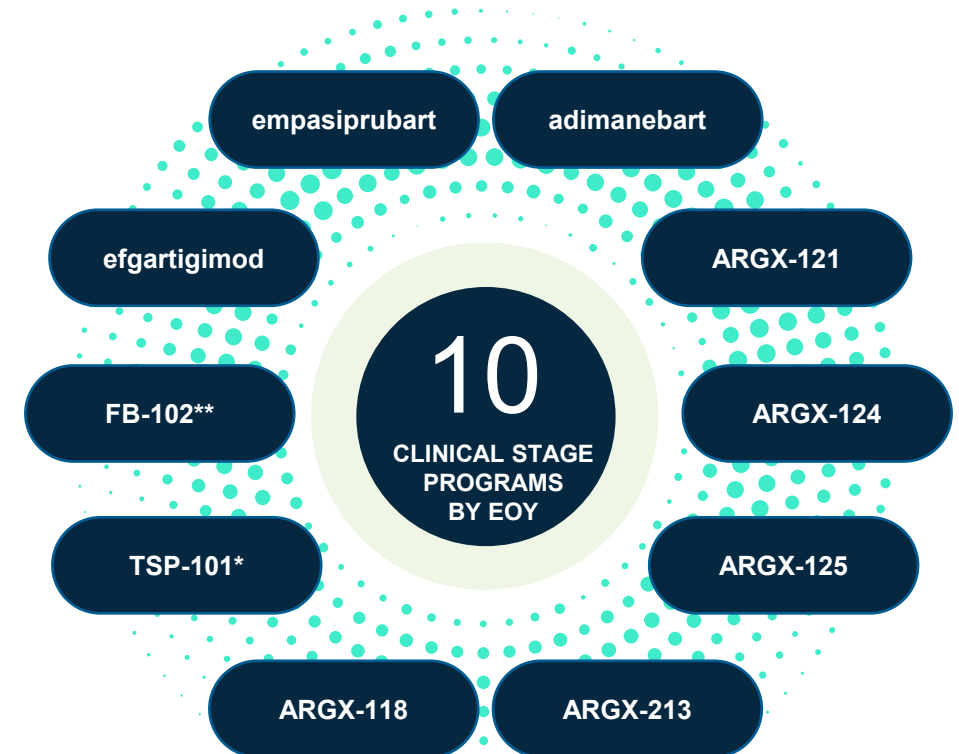
Today's announcement



Delivering Long-Term Growth Across Immunology Pipeline



This is just the beginning...



*Option for future acquisition
**Pending ARGX pipeline inclusion upon deal completion