# Together We Discover

Reaching Patients Through Immunology Innovation



Third Quarter Financial Results and Business Update october 27, 2022

# Forward Looking Statements

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# Building a Leading Sustainable Immunology Company

Driving innovation
mission with an
entrepreneurial
spirit and commitment
to a strong culture

Building Company We Want to Work For Committed to our Patients and Supporters

Global VYVGART launch

\$227M

in product revenues in first three quarters

Antibody Engineering Platform

### **8 Programs**

demonstrated human proof-of-concept

Rooted in Science through our IIP

Enviable Immunology Pipeline **12** 

#### **Autoimmune Diseases**

To be under evaluation between efgartigimod and ARGX-117

We believe the future belongs to those who collaborate best



## **VYVGART Launch Shows Continued Momentum**

Addressing the unmet need in gMG

> **2K** patients on VYVGART globally

\$131M

3Q Net Product
Revenues

Backed by solid science and data









Significant physician and patient demand

Broad coverage achieved



# Multiple Data Readouts Expected in 2023





# **Chronic Inflammatory Demyelinating** Polyneuropathy ADHERE Trial



**Identify patients with active CIDP** 

#### Screening

Confirmation of diagnosis by independent committee

≤4weeks

#### **Run-in period**

Worsening of disease within 12 weeks after drug withdrawal (INCAT, I-RODS, grip strength)

Newly diagnosed/ treatment naïve skip run-in period

≤13weeks

**Confirm IgG autoantibody** involvement

Assess efficacy & safety efgartigimod vs placebo

#### **Treatment period**

**Open-label** 

Stage A

Efgartigimod weekly SC

Up to 12 weeks,

Placebo-controlled

**Stage B** (Stage A responders only)

Placebo weekly SC

Efgartigimod weekly SC

Up to 48 weeks

Efficacy analysis based on relapse (adjusted INCAT)

Study endpoint with 88 relapse events in stage B

> N=sample size estimation ~120-130

Followed by **Open Label Extension** study

until clinical improvement (ECI)



#### **ADVANCE-IV Phase 3**

# Results Support Path Forward



Primary endpoint met

Statistically significant and clinically meaningful improvement in platelet counts over placebo

Meaningful patient benefit observed

- Fast and robust platelet count improvement over placebo
- Ability for every other week dosing confirmed

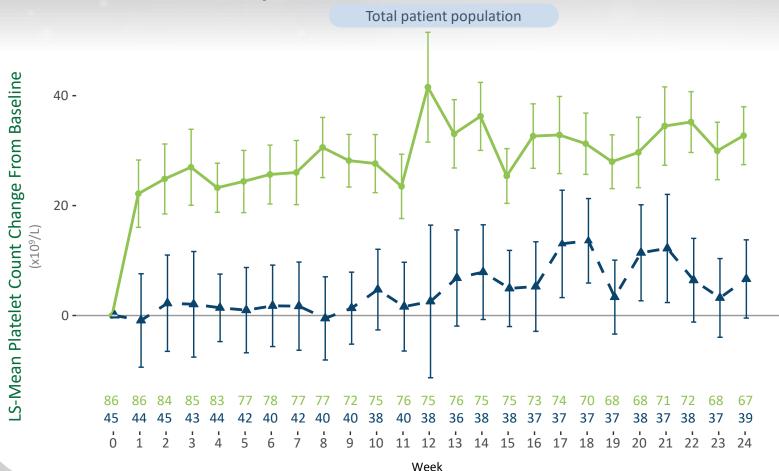
Favorable safety & tolerability observed

- Chronic administration of VYVGART was well-tolerated
- Safety profile consistent with previous clinical trials

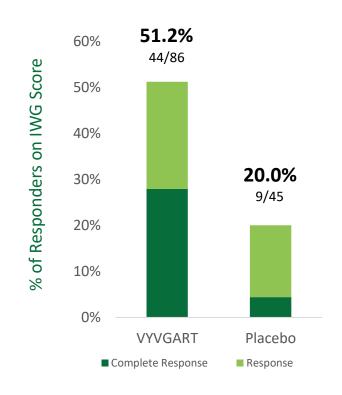


# Per IWG criteria, 51% of VYVGART Patients Showed Real-World Relevant Platelet Count Improvement in Absence of Bleeding

#### **Clear Separation Between VYVGART and Placebo**



International Workgroup (IWG) Criteria reflecting real-world treatment goals









# New Efgartigimod Translational Data

Demonstrating our scientific leadership in FcRn biology, providing new insights into pathophysiology of autoimmune skin blistering diseases and potential role of FcRn blockade







Maho-Vaillant M et al. FcRn Antagonism Leads to a Decrease of Desmoglein-Specific B Cells: Secondary Analysis of a Phase 2 Study of Efgartigimod in Pemphigus Vulgaris and Pemphigus Foliaceus. Front. Immunol. 13:863095. doi: 10.3389/fimmu.2022.863095

Zakrzewicz, Anna, et al. "Stabilization of Keratinocyte Monolayer Integrity in the Presence of Anti-Desmoglein-3 Antibodies through FcRn Blockade with Efgartigimod: Novel Treatment Paradigm for Pemphigus?." Cells 11.6 (2022): 942.

# ARGX-117 Blocks C2 Classical Lectin Mannose sugar C3 convertase C5 convertase

# ARGX-117: Sweeping Antibody Designed to Target Unique Intervention in Complement

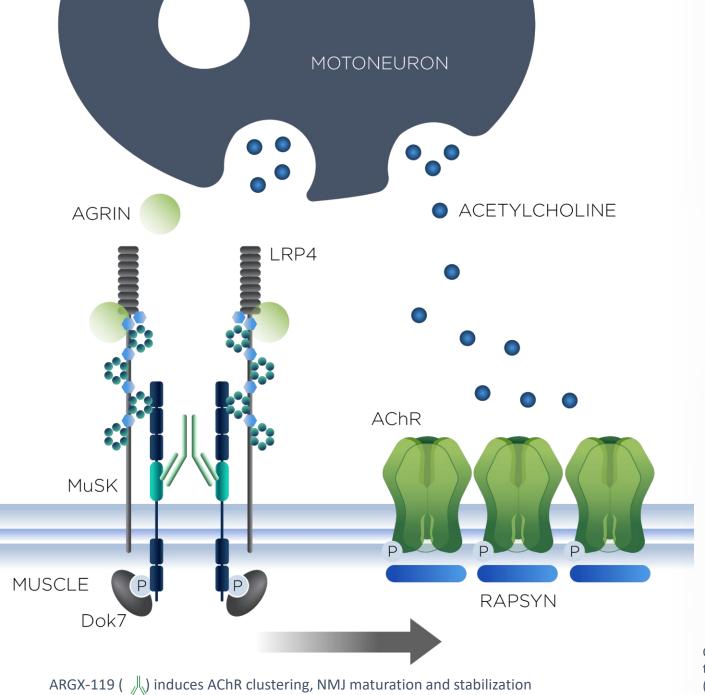
#### Targeting C2:

- Leaves alternative pathway intact against infection
- Blocks all complement effector functions

Multifocal Motor Neuropathy;
Phase 2 trial started

Delayed Graft Function in Kidney
Transplant





ARGX-119: MuSK Agonist with Broad Potential in Neuromuscular Disease

Oury, J., Zhang, W., Leloup, N. et al. Mechanism of disease and therapeutic rescue of Dok7 congenital myasthenia. Nature 595, 404–408 (2021). https://doi.org/10.1038/s41586-021-03672-3



# Pipeline Growth Driven By Immunology Innovation Program



# Global VYVGART Net Sales

(in millions \$)	Q1 FY22	Q2 FY22	Q3 FY22	9 months ended Sept 30, 2022
US	21.2	73.2	124.1	218.5
Japan	-	1.5	6.0	7.5
Europe	-	-	0.6	0.6
Distributor markets	-	0.1	0.6	0.7
Total Product Net Sales	21.2	74.8	131.3	227.3

Strong quarter-over-quarter growth in global VYVGART revenues



# **Third Quarter 2022 Financial Results**

	Three months ended September 30		Nine months ended September 30	
(in millions of \$)				
	2022	2021	2022	2021
Product net sales	131.3	- *	227.3	
US	124.1	-	218.5	-
Japan	6.0	-	7.5	-
Europe	0.6	-	0.6	-
Distributor Markets	0.6	-	0.7	_
Collaboration revenue and other	15.2	7.1	35.8	505.7
Total operating income	146.5	7.1	263.2	505.7
Cost of sales	(10.3)	-	(16.6)	-
R&D expenses	(236.7)	(139.4)	(515.6)	(413.3)
SG&A expenses	(108.2)	(80.6)	(336.8)	(210.2)
Total operating expenses	(355.1)	(220.1)	(869.1)	(623.6)
Other (expenses) / income	(24.1)	(20.7)	(62.8)	(52.6)
(Loss) / Profit for the period	(232.7)	(233.6)	(668.7)	(170.4)

Cash balance as of September 30, 2022 is approximately \$2.4B



# Global gMG Launch Progressing







SC BLA Filed



Japan Launched May 9, 2022

**Europe**Launched in Germany
September 1, 2022

**Gulf States** (GenPharm)

**Central and Eastern Europe** (Medison)

Approvals expected throughout 2023: **Canada** 

**China** (Zai)

**Israel** (Medison)

# **Executing on VYVGART Launch Priorities**

#### Meeting our stakeholders where they are





**Empower Patients** to Demand Better



Best-in-Class Patient Support





Rapid HCP Adoption of **VYVGART** 





Enable Appropriate Access

MORE THAN 50%

**GROWTH IN PATIENTS ON VYVGART** 



**Broad prescriber** base;

Shift to broad adoption key indicator of growth trajectory

**Broad coverage in** place;

~90% US policies are favorable



# Differentiated Treatment Options for gMG Patients



# Reaching Patients With VYVGART

I completed my first cycle of VYVGART. I scored a "0" on the MG-ADL. It's been nine weeks since I completed that first cycle, and I haven't needed a subsequent cycle yet.

- VYVGART® Patient



