

**MOMENTA**



# Third Quarter 2019 Financial Results

*October 31, 2019*



# Agenda

## Introduction

- Patty Eisenhaur, Vice President, Investor Relations and Communications

## Corporate Update

- Craig Wheeler, President and Chief Executive Officer

## Third Quarter 2019 Financial Results

- Michelle Robertson, Chief Financial Officer

## Closing Remarks

- Craig Wheeler, President and Chief Executive Officer

## Question & Answer Session

# Forward-Looking Statements

This presentation contains forward-looking statements about our financial outlook, business plans and objectives and other future events and developments. These forward-looking statements include, but are not limited to statements about our pipeline; the design, timing and goals of clinical trials and the availability, timing and announcement of data and results; the use, efficacy, potency, safety, tolerability, dosing convenience and commercial potential of our product candidates, including their potential as best-in-class agents; hypotheses regarding certain actions and effects of our product in clinical studies, the timing of regulatory submissions, potential regulatory approvals, development plans, and launches of our product candidates and products; market potential, reception, and product revenues of our products and product candidates; our priorities, goals and strategy; development design, timelines and strategies for our product candidates; our future financial expectations and non-GAAP operating expense guidance and our anticipated collaborative reimbursement revenues. Such forward-looking statements involve known and unknown risks, uncertainties, and other important factors, which could cause actual results to differ materially from those expressed or implied in such statements. These risks and uncertainties include, but are not limited to, unexpected regulatory decisions regarding any of these activities, unexpected expenses or inaccurate financial assumptions or forecasts; additional or increased litigation efforts by our competitors; insufficient resources or failure to prioritize competing projects and efforts; disputes with our collaboration partners; inability to successfully partner the development and commercialization of our product candidates; delays or unfavorable decisions of regulatory agencies; unfavorable regulatory guidance pronouncements; safety, efficacy or tolerability problems with our product candidates; unexpected negative results of clinical trials and competition for targeted indications or within targeted markets. Risks and uncertainties also include those referred to under “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 filed with the Securities and Exchange Commission (SEC), as well as other documents that we may file from time to time with the SEC. Information provided in this presentation speaks only as of the date of this presentation, and we assume no obligation to update forward-looking statements to reflect events or circumstances occurring after this presentation.

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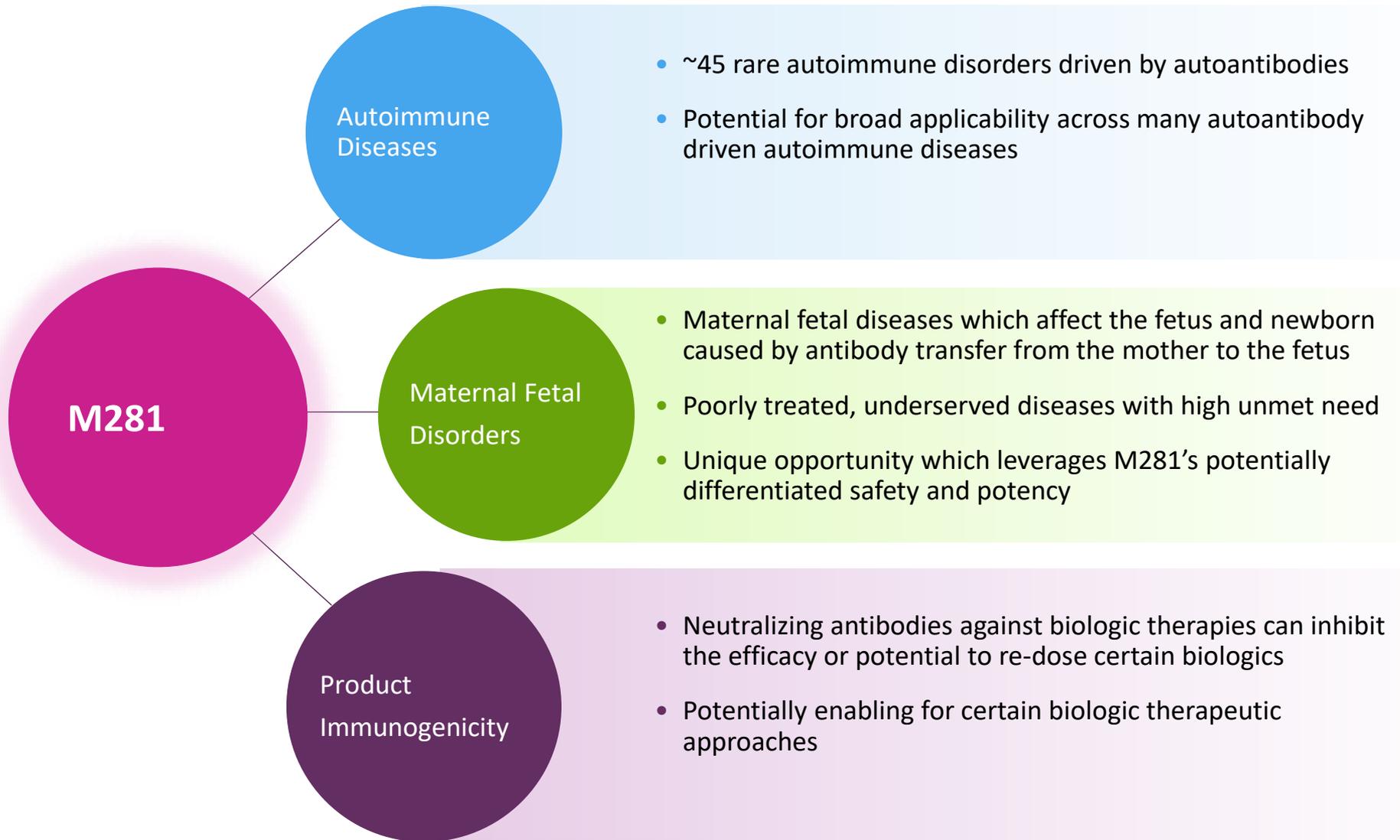
- Michelle Robertson, Chief Financial Officer

## Closing Remarks

- Craig Wheeler, President and Chief Executive Officer

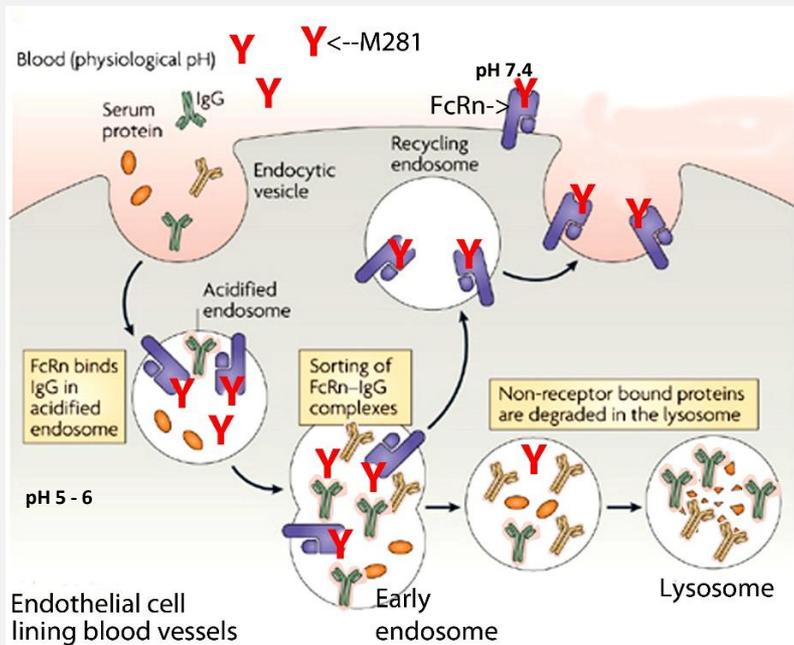
## Question & Answer Session

# Nipocalimab (M281) has Potential Commercial Opportunity in Three Broad Areas



# FcRn Inhibition an Innovative Approach to Reduce Pathogenic IgG Antibodies; Three Areas with Broad Market Potential

FcRn inhibition decreases circulating IgG levels, including pathogenic antibodies



FcRn inhibition may impact many auto-antibody driven autoimmune disorders

Autoimmune Diseases

- ~45 rare autoimmune disorders driven by autoantibodies
- 1-2 million patients (US)

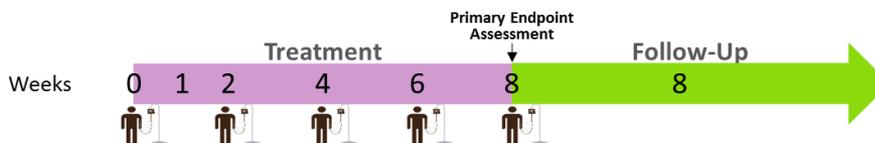
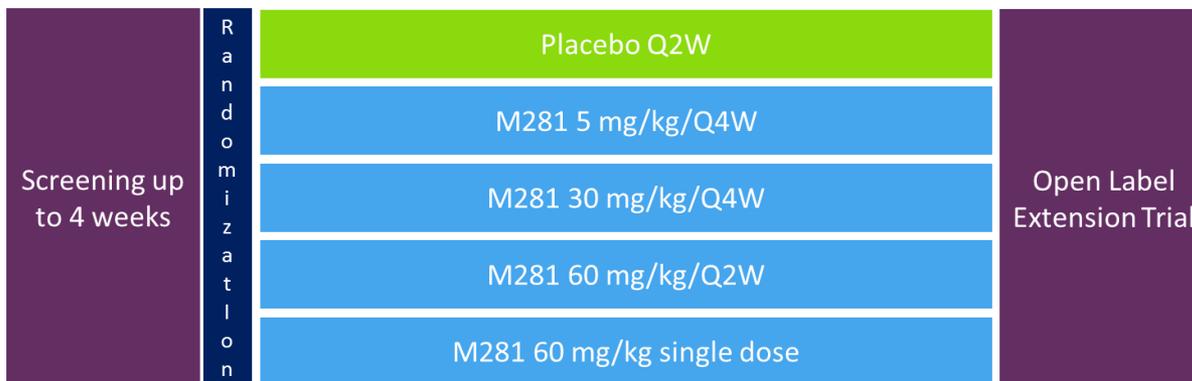
Fetal Maternal Disorders

- Several fetal maternal diseases, significant morbidity / mortality
- 10,000-20,000 patients (US)

Product Immunogenicity

- Neutralizing antibodies against biologic therapies
- Thousands of patients

# Vivacity-MG Phase 2 Study Ongoing



## Objectives

- Increased potency (IgG reduction) drives efficacy
- Favorable dosing: 1x/month or bi-monthly
- Favorable safety profile, consistent with Phase 1

Top-Line Data Expected 2Q/3Q 2020

# Nipocalimab (M281): Warm Autoimmune Hemolytic Anemia (wAIHA)

## Severe Debilitating Disease

- Rare disorder characterized by the destruction of red blood cells due to the presence of pathogenic IgG autoantibodies
- Characterized by severe anemia, weakness and fatigue
- Complications can impact quality of life
  - Risk of premature death, up to 8%

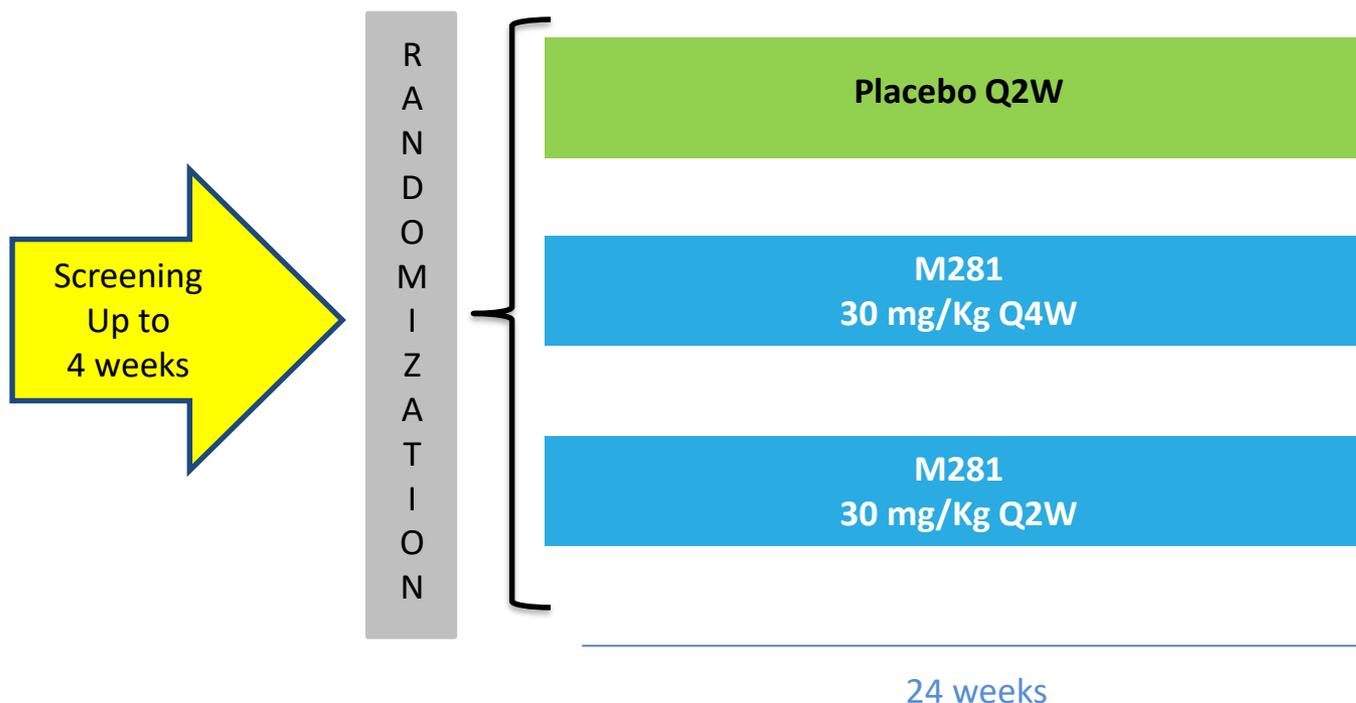
## Significant Unmet Need

- About half of cases are idiopathic, others are secondary to other conditions (e.g., autoimmune disorders, cancer)
- Estimated prevalence of 45,000 in U.S.
- Currently no FDA approved treatments
- Current standard of care:
  - Rescue transfusions
  - Corticosteroids
  - Immunosuppressants
  - Splenectomy

# Energy Trial: Phase 2/3 Adaptive Trial in Warm Autoimmune Hemolytic Anemia (wAIHA)

- Randomized, double-blind, placebo-controlled, multi-center, adaptive Phase 2/3 study
  - Primary or secondary wAIHA
  - 90 patients, 24-week treatment period
  - 1<sup>o</sup> Endpoint: Patients with a clinically relevant increase in hemoglobin
  - 2<sup>o</sup> Endpoints: Markers of hemolysis and fatigue
- FDA Fast Track designation granted
- Sites being activated and patient recruitment underway
- Interim analysis (IA) will provide decision on study continuation vs futility or termination of one of the groups.
  - Other than study termination, results of the IA will not be known by Momenta

# Energy: Adaptive Phase 2/3 Study Design

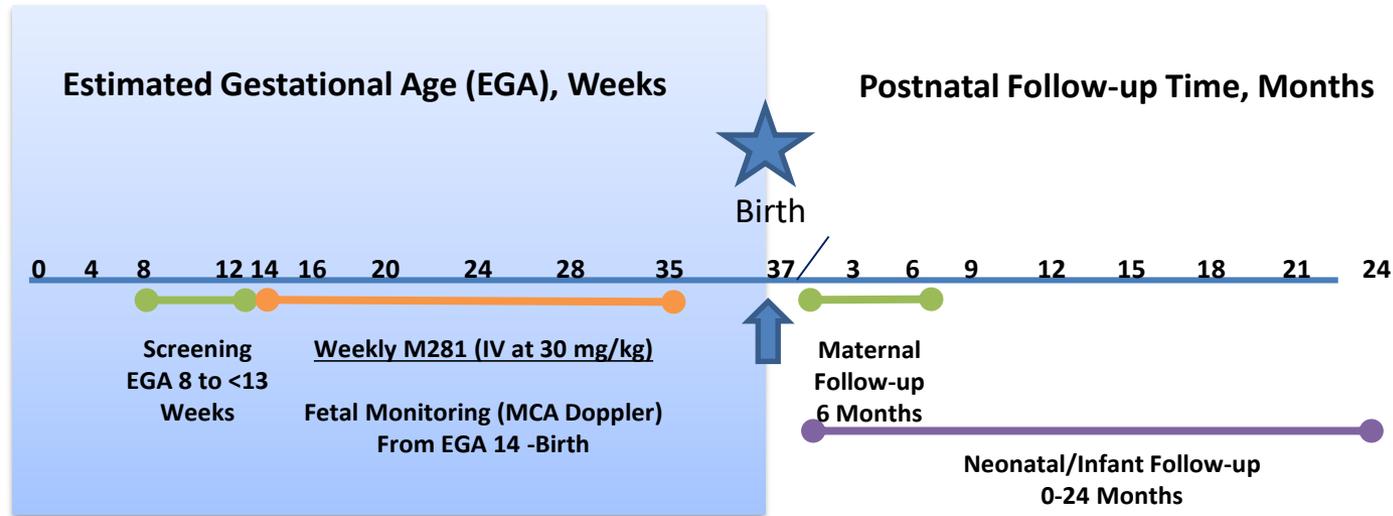


- 90 patient study
- Adaptive design provides flexibility and maximizes data
- Readout expected at the end of 2021
- FDA Fast Tract Designation

# Infusion Study Results Supports Significant Reduction in Infusion Rates

- N=40 healthy volunteers (30 on drug and 10 on placebo)
- Safety and tolerability profile confirmed with no drug related infusion reactions and no clinically relevant abnormalities in labs, vitals or ECGs
- Data supports infusion times as low as:
  - 7.5 min. for 30 mg/kg
  - 15 min. for 60 mg/kg
- Shorter infusion times facilitates trial recruitment reducing patient and facility burden
  - Incorporating into wAIHA and MG studies
- Data supports nipocalimab's best-in-class profile

# Unity: Phase 2 Study of Nipocalimab in Early-Onset HDFN, Designed to Show Full Blockade of FcRn, ~85% IgG Reduction



**Primary Endpoint:** Proportion of patients with live birth at or after Gestational Age 32 without IUT N=15

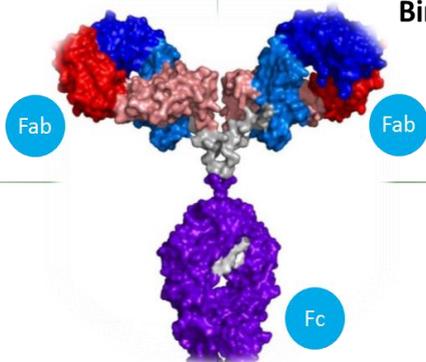
- FDA Fast Track designation
- Proof-of-concept data expected in 2021; may offer pathway to accelerated approval
- Potential to transform the treatment landscape in HDFN
- Study to validate nipocalimab for treatment of additional fetal-maternal disorders

# Nipocalimab (M281): Purposefully Designed for Best-in-Class Potential

## Designed with Best-in-Class Potential

High Affinity Binding to FcRn

Epitope Specific to IgG Binding Site



pH Resistant Binding

Engineered Effectorless Design

Fully Human IgG1 Monoclonal Antibody

## Targeting a Best-in-Class Profile

Highest IgG reduction



Potential for optimal efficacy

100% receptor occupancy



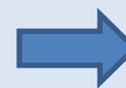
Critical for certain indications requiring maximum blockage

Potency and short infusion drives flexible dosing approaches



Testing IV SC in development

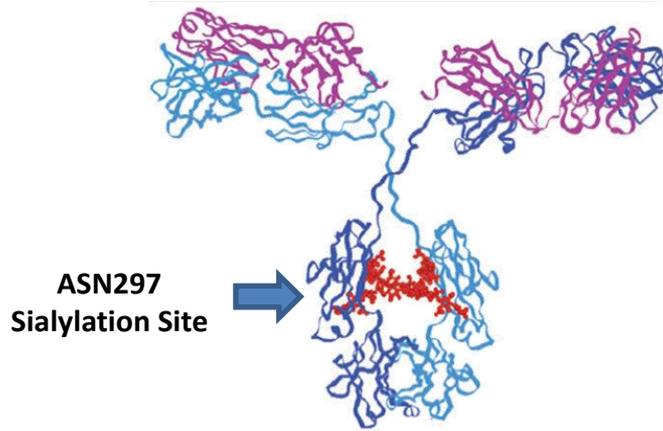
Maternal/Fetal studies



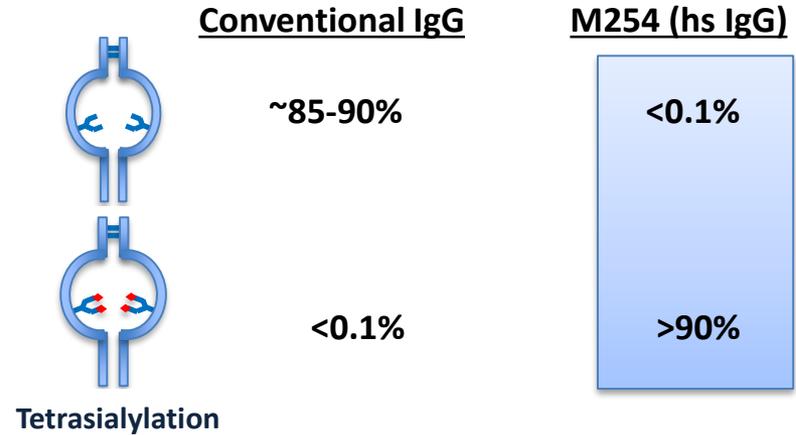
Access to the broadest market

# M254 (Hypersialylated IgG) is Significantly More Potent than IVIg in Models

Sialylation is a natural, regulated process in the glycosylation site of the Fc Region

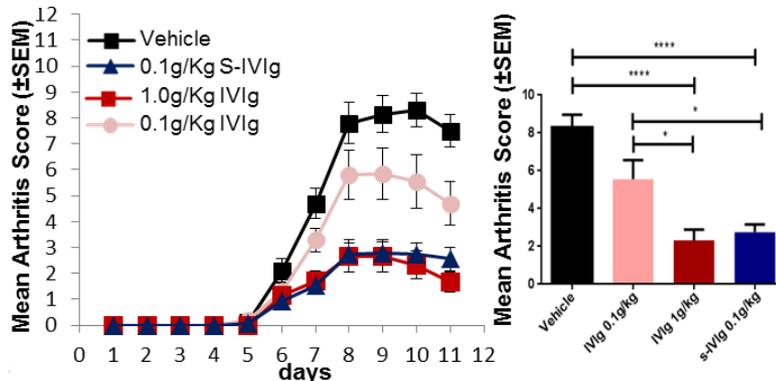


M254 is a hypersialylated IgG made from conventional IgG



Hypersialylation enhances anti-inflammatory properties of IgG

Increased potency vs conventional IgG is observed in all models tested



- Collagen Antibody-Induced Arthritis
- KBxN Arthritis
- ITP
- Epidermolysis Bullosa Acquisita Pemphigus

# M254: Potentially Superior Therapeutic Option vs. IgG Products for Immune-Mediated Conditions

## Convenience

- Shorter infusion times
- Potential sub-C dosing
- Increased convenience

## Safety

- Decreased dose may reduce AEs
- Potential steroid-sparing

## Potency

- Greater immune modulation
- Increased efficacy

**Recommended loading dose for IVIg in CIDP:**

66 hours over several days

**Selected IVIg key adverse events:**

Headaches, hypertension, fatigue, nausea, fever

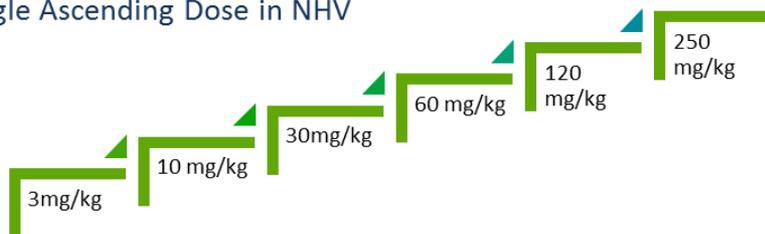
**M254 Potential Indications:**

IVIg Approved (e.g., ITP, CIDP) or reimbursed

# Phase 1/2 Study in ITP Designed to Establish Dose-Equivalent Potency vs IVIg, Safety and Tolerability for M254

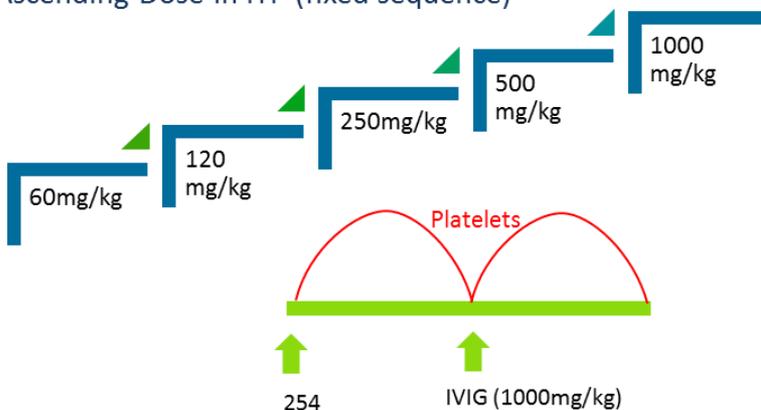
## PART A

Single Ascending Dose in NHV



## PART B

Single Ascending Dose in ITP (fixed sequence)



## PART C

Cross-Over in ITP

IVIg 1000 mg/kg

M254 High dose

IVIg 1000 mg/kg

M254 Low Dose



## PART D

Multiple Dose in ITP

M254 Dose TBD



- Proof-of-concept data expected in 1H 2020

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	Q3 2019	Q3 2018
GAAP Net Loss	\$44.5M	\$50.3M

	Q3 2019	Q3 2018
Product Revenue	\$5.6M	\$13.6M
Research & Development Revenue	\$0.8M	\$1.3M
Total Revenues	\$6.4M	\$14.9M
R&D Expenses	\$46.1M	\$30.7M
G&A Expenses	\$20.1M	\$20.4M
Restructuring	--	\$15.5M
Gain on lease modification	\$(13.7)M	--
Total Operating Expenses <sup>(2)</sup>	\$52.5M	\$66.7M

# Third Quarter 2019

## Non-GAAP Operating Expense & Cash Position

	3 Mos Ended September 30, 2019 (Actual)
Non-GAAP Operating Expense <sup>(1)</sup>	\$45.7M

- (1) Non-GAAP operating expense is total operating expenses, less stock-based compensation expense, restructuring expense and collaborative reimbursement revenues. While Momenta believes this non-GAAP financial measure is useful to investors because it provides greater transparency regarding Momenta's operating performance, it should not be considered a substitute or an alternative to GAAP total operating expense. For the three months ended September 30, 2019, stock-based compensation was \$6.7 million and reimbursement revenue from collaboration partners was \$0.1 million.

	Q3 2019	Q4 2018
Cash, cash equivalents, marketable securities	\$325.9M	\$449.1M

# Quarterly 2019 Financial Guidance

	2019 Quarterly Guidance <sup>(2)</sup>
Non-GAAP Operating Expense <sup>(1)</sup>	~\$50M - \$60M

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- (2) The Company has not provided a GAAP reconciliation for its forward-looking non-GAAP annual or quarterly operating expense because Momenta cannot reliably predict without unreasonable efforts the timing or amount of the factors that substantially contribute to the projection of stock compensation expense, which is excluded from the forward-looking non-GAAP financial measure. We do not anticipate significant restructuring costs in future periods. The Company expects collaborative reimbursement revenues to be approximately \$0 - \$2 million per quarter in 2019.

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# 2019: A Year of Operational Execution

Portfolio	Program	Goal/Milestone	Expected Clinical Readout
Novel Drugs	M281 (anti-FcRn)	Enroll MG and HDFN studies Launch wAIHA study	MG: 2Q/3Q: 2020 HDFN: 2021 wAIHA: end of 2021
	M254 (hslgG)	Advance Phase 1/2 proof of concept study in ITP	ITP: 2020
	M230 (rFc multimer)	Phase I study ongoing (by partner CSL)	
	Research	Advance CSL research collaboration	
Biosimilars	M710 (b-EYLEA® candidate)	Advance Phase 3 towards completion	

**Fourth Quarter 2019 Expense Guidance: \$50-60 million**

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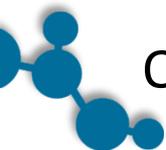
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