

Momenta Pharmaceuticals, Inc.

August 2017

### **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 use, efficacy, and commercial potential of our products and product candidates; the timing of clinical trials and the availability and timing of reporting results; the timing of regulatory submissions, regulatory approvals and launches of our product candidates, including Glatopa® 40 mg (glatiramer acetate); statements regarding work being done to bring Glatopa 40 mg to market; our priorities, goals and strategy; potential future out-licensing/collaborations/partnerships; and our development timelines. 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 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; delays or unfavorable decisions of regulatory agencies; unfavorable regulatory guidance pronouncements; safety, efficacy or tolerability problems with our product candidates; 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, 2017 that we 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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### **Momenta Today**



### **Analytic Data-Driven Approach**

- Proven expertise in high-resolution analytics, biological characterization and process engineering
  - First to achieve FDA approval of complex generic versions of LOVENOX® and COPAXONE® 20mg
- Provides advantage in biosimilar and novel drug development



### **Diverse & Growing Pipeline**

- Manages risk
- Maximizes upside potential
- Well funded with capital allocation flexibility

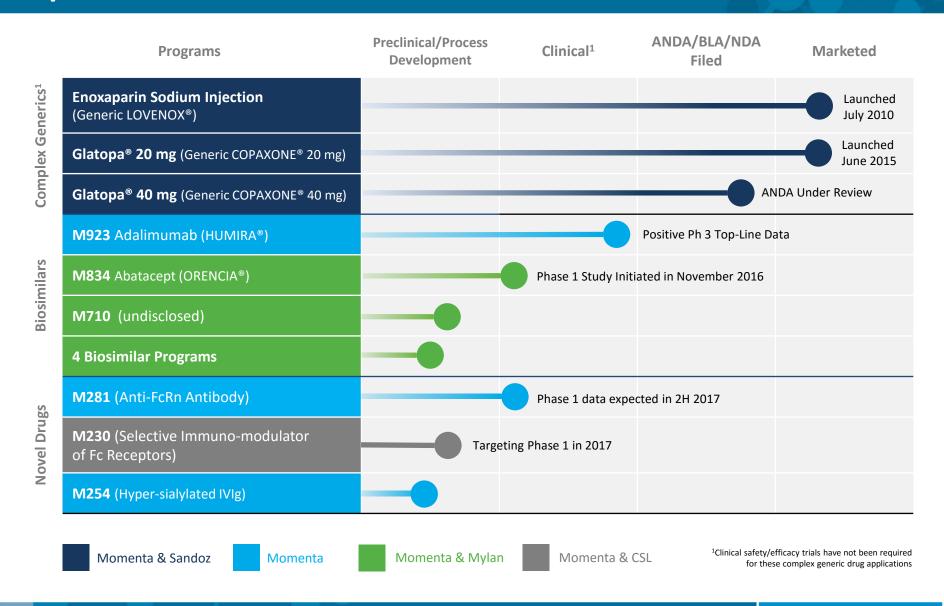


### **Collaborations with Industry Leaders**

- Building our business through strong collaborations
  - CSL, Mylan, Sandoz

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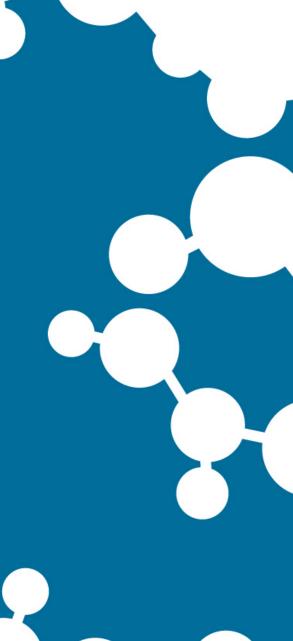
## Momenta's Technology Platform has Generated a Robust Pipeline of Commercial Products & Product Candidates



## **Complex Generics**

**Biosimilars** 

**Novel Drugs for Autoimmune Indications** 



# Potential for Glatopa® 40 mg Approval and Launch in 2H 2017

- February 16, 2017 Pfizer, Sandoz's contracted fill/finish manufacturer of Glatopa, notified us they had received a warning letter related to its McPherson, Kansas manufacturing facility
  - Glatopa not cited by FDA in the observations that led to the warning letter
  - Warning letter states that the FDA "may" withhold approvals until successful resolution
- No outstanding questions from the FDA regarding Sandoz's Glatopa 40 mg ANDA
- Pfizer submits comprehensive response to FDA warning letter
  - Response indicates that many of the commitments Pfizer made to the FDA following the May-June 2016 inspection have been completed
  - Pfizer is implementing a comprehensive quality improvement plan to address outstanding observations
- Momenta is working closely with Sandoz to be able to bring Glatopa
   40 mg to the market as soon as possible
  - Evaluating potential second Glatopa fill/finish manufacturers

# Glatopa®: First FDA-Approved, Substitutable Generic Daily COPAXONE® 20 mg for Multiple Sclerosis

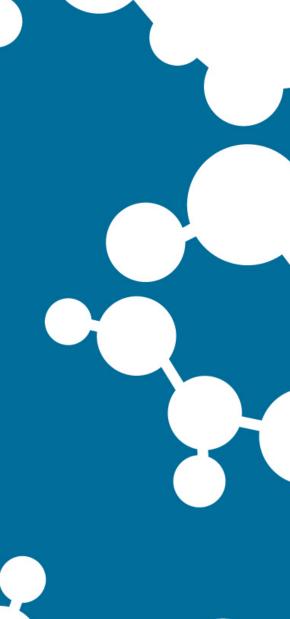
- Sandoz commenced U.S. launch of Glatopa 20 mg in June 2015
- Momenta Q2 2017 profit share of \$19M compared to \$21M in Q1 2016
- On July 1, 2017 Momenta earned a \$10M milestone payment from Sandoz for Glatopa achieving a second year in the U.S. as the sole FDA-approved generic COPAXONE and a certain level of contractually defined profits
- Glatopa prescriptions represent ~40% of the 20 mg glatiramer acetate market in the U.S.<sup>1</sup>
- Sandoz has an established patient support services hub
- Sandoz has established relationships with wholesalers, retailers, payors, PBM's and plans

<sup>&</sup>lt;sup>1</sup> Source: Symphony Health Solutions prescription data plus Sandoz internal estimates to include key Glatopa accounts not reported in Symphony.

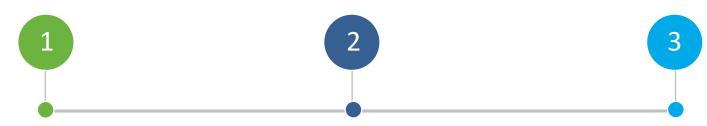
**Complex Generics** 

**Biosimilars** 

**Novel Drugs for Autoimmune**<br/>**Indications** 



## **Our Approach to Biosimilars**



## Build a broad and diverse portfolio

Portfolio of complex biologics including mAbs and fusion proteins

Capture scale, technology and regulatory synergies

Smooth revenue flow

# Gain competitive advantage through our scientific approach and regulatory strategies

Biocharacterization platform, analytic toolset and process control offer potential added-value opportunities:

Extrapolation of indications, reduced trial scope and interchangeability designation

Process and scale-up precision to engineer in quality and improve P.O.S.

Integrated regulatory and legal strategy to launch at market formation

# Ensure products are positioned to capture the global opportunity through collaborations

Identify and collaborate with strategic partners with:

Global commercial capabilities

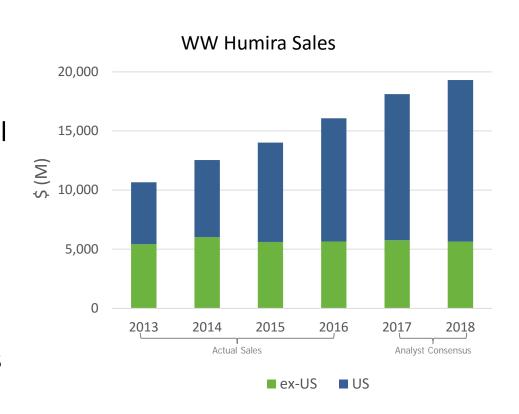
Low cost manufacturing strategies



# M923, Biosimilar HUMIRA® (adalimumab) <u>Candidate, with Positive Phase 3 Clinical Trial Results</u>

## Regained global rights to M923 from Shire and received a one-time payment of \$51M to fund program through Q3 2017

- Working toward first submission for marketing approval in Q4 2017
- Preparing for first commercial launch in U.S. as early as 2020 timeframe, subject to marketing approval and patent considerations
- Potential to re-partner M923 for enhanced deal economics

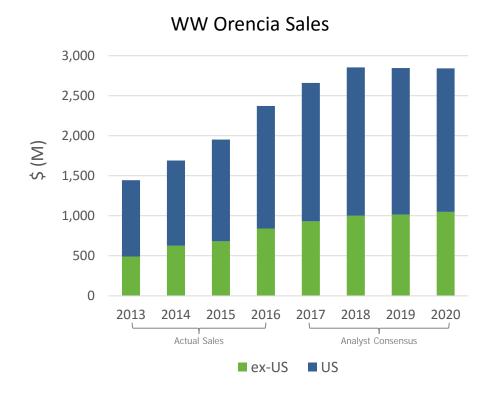


# M834: Biosimilar ORENCIA® (abatacept) Candidate Currently in Phase 1 Clinical Trial

## Complex fusion protein with limited biosimilar competition



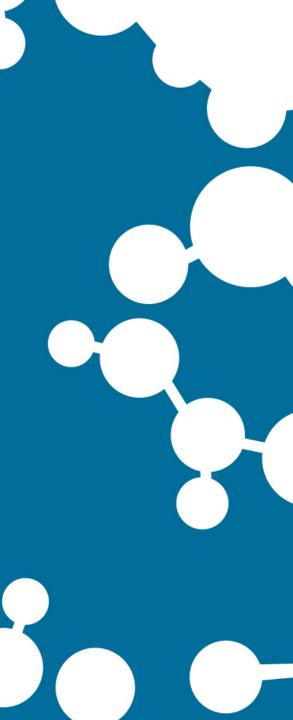
- Plan to report top-line data from Phase 1 trial in 2H 2017
- BMS '239 formulation patent upheld in IPR proceeding; decision appealed to the U.S. Court of Appeals with a potential hearing in Q4 2017



**Complex Generics** 

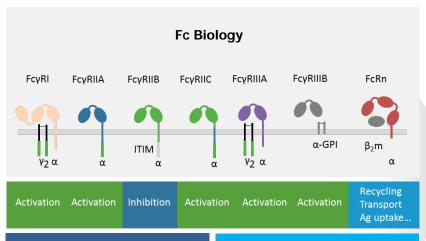
**Biosimilars** 

Novel Drugs for Autoimmune Indications



# Our Fc Biology Platform Yields Multiple Candidates Targeting a Broad Set of Autoimmune (AI) Indications

### **Platform**



#### **Protein Engineering**

- Sialylation
- Fc multimer
- Fc Engineering

#### **Complex Analytics**

- Disease
- Targets
- Patient

### **Portfolio**

M230 (SIF3)

M281 (Anti-FcRn)

M254 (hs-IVIg)

Next-Generation Molecules

### **Opportunity**

#### **Rare Al Diseases**

Over 70 distinct disease indications

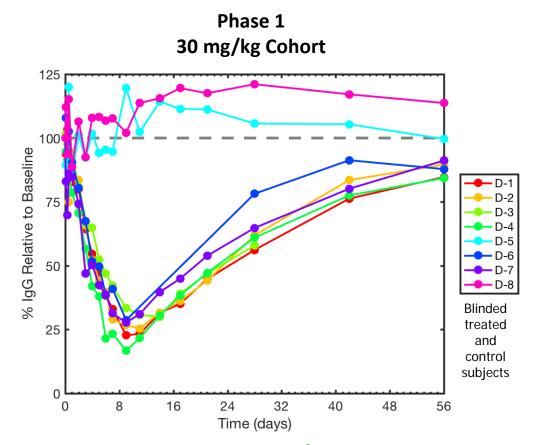
#### **Prevalent Al Diseases**

RA, Psoriasis, Psoriatic arthritis, Crohn's, Ulcerative colitis, Ankylosing spondylitis

## Other Fc- mediated Diseases

Immuno-oncology, Immunology, Oncology

# M281: Fully Human Monoclonal Antibody (mAb) Targeting the Neonatal Fc Receptor (FcRn) in Phase 1 Study

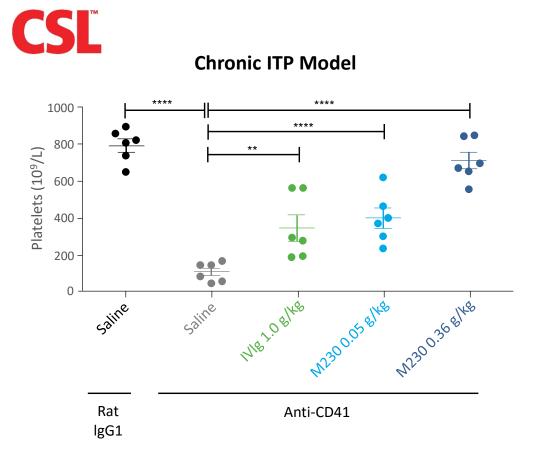


A single dose of 30 mg/kg achieved up to 80% reduction of circulating IgG

- M281 rapidly reduces circulating IgG antibodies in non-human preclinical and first in human studies
- Potential to use acutely or intermittently for autoantibody clearance across a range of IgGdriven autoimmune diseases
- Completed Phase 1 single ascending dose study in healthy volunteers and multiple ascending dose study ongoing
- Plan to report data from Phase 1 healthy volunteer study in 2H 2017

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# M230, Selective Immunomodulator of Fc Receptors (SIF3), in Collaboration with CSL



Source: Ortiz et al. Science Translational Medicine, 16 November 2016, Volume 365, pp 1-13

- Homogenous recombinant Fcderived drug candidate designed with enhanced avidity and affinity for Fc receptors
- M230 shows higher potency and efficacy at a lower dose than IVIg in preclinical chronic ITP model
- Engineered a high-producing GMP-manufacturing cell line and completed GLP toxicology
- Development plan in place; targeting a clinical trial in Q4 2017

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# CSL Agreement & Collaboration Financial Terms - Effective as of 2/17/17

### **M230 License Agreement**

- \$50M upfront payment to MNTA
- Up to \$550M in contingent milestone payments
- Sales-based royalty payments ranging from mid-single to lowdouble digits
- Option to participate in 50% or 30% cost/profit share arrangement in the United States
  - Royalties and milestones are payable outside the U.S.
  - Option to co-promote in the U.S.

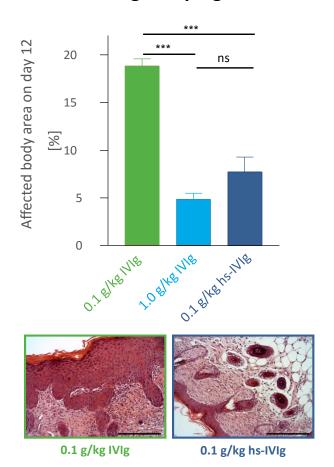
### Fc Multimer Research Collaboration

- Pre-agreed sales-based royalty payments and development milestones for one research candidate and others to be negotiated
- Option to participate in 50% or 30% cost/profit share arrangement in the United States
  - Royalties and milestones are payable outside the U.S.
  - Option to co-promote in the U.S.

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## M254 (hsIVIg), Shows up to 10x Enhanced Anti-Inflammatory Activity in Preclinical Autoimmune Models

#### **Skin Blistering Pemphigoid Model**

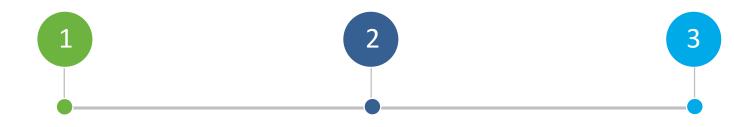


\*\*\*=p <0.001, ns= no significance

Source: Washburn et al. PNAS 2015 112 (11) E1297-E1306

- Sialylation of the Fc region of IgG mediates the anti-flammatory effects of IVIg
- Momenta has developed a process to maximize sialylation to the Fc and maximize therapeutic effects
- M254 has the potential to be a more potent, subcutaneous alternative to IVIg
- Plan to initiate an IND-enabling toxicology study in 2017 and to initiate a clinical trial in 2018

### Well Funded with Capital Allocation Flexibility



#### **Cash Position**

\$457M at the quarter ended June 30, 2017

#### **Cash Inflows**

Glatopa® 20 mg revenues from Sandoz profit share

Potential future Glatopa 40 mg revenues from Sandoz profit share

Current collaborations include potential future development and commercial milestone payments

Potential future outlicensing/collaborations (M923, novel programs)

#### **Disciplined Cash Burn**

Stage-gate approach to new development programs

Optionality to co-fund development (M230) and commercialization (biosimilars and M230) of current partnered programs

### **Momenta's Near-and Long-Term Goals**

#### **BIOSIMILARS**

### 2017

- M923, biosimilar HUMIRA® candidate, working toward submission for marketing approval in Q4 2017
- Report M834, biosimilar
   ORENCIA® candidate, Ph 1 data
   and progress towards Ph 3 study

#### 2020+

- M923, biosimilar HUMIRA® candidate, on the market
- Launch 1-2 biosimilar product candidates per year

#### **COMPLEX GENERICS**

- Potential FDA approval of ANDA for Glatopa® 40 mg, generic COPAXONE® 40 mg
- Potential for Sandoz launch of Glatopa 40 mg

 Glatopa 40 mg, generic COPAXONE® 40 mg, on the market

#### **NOVEL DRUGS**

- Complete M281, anti-FcRn antibody, Ph 1 clinical trial and report data
- Initiate M230, SIF3, Ph 1 clinical trial
- Initiate IND enabling toxicology study for M254

 Launch 1-2 novel drugs for autoimmune indications



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