## Coherus BioSciences

2018 CANTOR GLOBAL HEALTHCARE CONFERENCE OCTOBER 2, 2018



### **Forward Looking Statements**

This presentation does not constitute or form any part of any offer for sale or subscription of or solicitation or invitation of any offer to buy or subscribe for any securities. Neither this presentation nor any part of it shall form the basis of or be relied upon in connection with any contract or commitment whatsoever. Specifically, this presentation does not constitute a "prospectus" within the meaning of the Securities Act of 1933, as amended. Except for the historical information contained herein, the matters set forth in this presentation, including statements regarding Coherus' plans, potential opportunities, expectations, projections, goals, objectives, milestones, strategies, product pipeline, clinical studies, product development, release of data and the potential benefits of its products under development are forwardlooking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, Coherus' expectations regarding approval of the biologics license application ("BLA") and the U.S. Food and Drug Administration's action date: Coherus' expectations regarding market approval in the U.S.: Coherus' ability to enter into commercial collaborations in ex-U.S. territories; Coherus' plan to initiate U.S. commercial launch for CHS-1701 (UDENYCA™ (pegfilgrastim-cbqv)); Coherus' plan to initiate the clinical development of CHS-3351; Coherus' expectation to continue the preclinical development of CHS-2020; Coherus' ability to pursue manufacturing objectives of CHS-1420 in support of a BLA; and Coherus' plan to secure a U.S. commercial launch for of CHS-1420. Such forward-looking statements involve substantial risks and uncertainties that could cause Coherus' actual results, performance or achievements to differ significantly from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties inherent in the clinical drug development process; the risks and uncertainties of the regulatory approval process, including the timing of Coherus' regulatory filings; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' biosimilar drug candidates; and the risks and uncertainties of possible patent litigation. All forward-looking statements contained in this presentation speak only as of the date on which they were made. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus' business in general, see Coherus' Quarterly Report on Form 10-Q for the three and six months ended June 30, 2018 and its future periodic reports to be filed with the Securities and Exchange Commission.

## Agenda

- Company Summary
- UDENYCA™ (pegfilgrastim-cbqv)
- Broad Unpartnered Pipeline



## Coherus BioSciences A Leading Biosimilars-focused Biologics Company

#### **Biologics Platform**







#### **Pipeline Opportunity**

Targeting ~\$40 billion in biologics revenues facing patent expiration by 2023

#### **Team** Capability

**Proven development** and commercialization competency

**AMGEN** 

Genentech

**Tularik** 



#### 2018 Key Catalysts

**UDENYCA**<sup>TM</sup> (pegfilgrastim-cbqv)

- ✓ Approved in E.U.
- Patent dance completed
- BLA resubmitted
- U.S. FDA approval and launch in the U.S.



### Platform: Long-Term Value Creation from 2018 to 2025

#### Oncology

- UDENYCA<sup>TM</sup> well positioned to compete in largest oncology biologic market in the U.S.
- Good biosimilar adoption dynamics in pegfilgrastim market
- Favorable reimbursement changes became effective in Q1 2018

#### **Anti-TNFs**

- CHS-1420 adalimumab (Humira) biosimilar U.S. market entry after invalidation or expiry of formulation patents in August 2022
- Evaluating strategic options for CHS-0214 etanercept (Enbrel) biosimilar

#### **Ophthalmology**

- CHS-3351 ranibizumab (Lucentis) biosimilar initiating clinical development in 2018
- CHS-2020 aflibercept (Eylea) biosimilar initiated preclinical development

Global Market in 2017

~\$5 billion

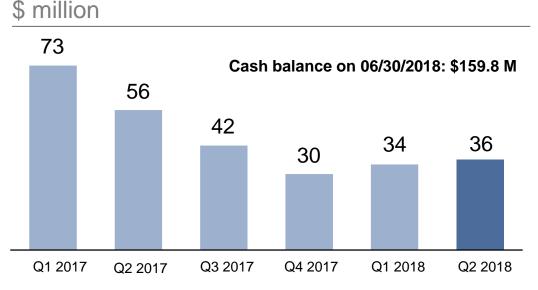
~\$25 billion

~\$10 billion



### **Disciplined Cash Use Until Approval**

### Updated quarterly use of cash in operations



- Demonstrated cash and financial control
- Temasek funding:
  - First \$75 million tranche completed in Q3 2017
  - Second \$75 million tranche projected post UDENYCA™ FDA approval
- Key investments in UDENYCA™ inventory build



## Agenda

- Company Summary
- UDENYCA™ Pegfilgrastim Biosimilar
- Broad Unpartnered Pipeline



### UDENYCA™ Pegfilgrastim Biosimilar: Consistent Progress, Tracking to Nov 3, 2018 Action Date

#### **Mitigate Key Issues**

- Develop and validate greater sensitivity immunogenicity assay
- Address manufacturing requests
- Conduct FDA meetings to review immunogenicity and CMC-related issues

#### **Prepare and File Resubmission**

- Completed sample testing
- Resubmitted BLA after receipt of FDA meeting minutes and integration of results; file was accepted and acknowledged mid May 2018
- Submitted Day 180 List of Outstanding Issues

#### Review and Approvals

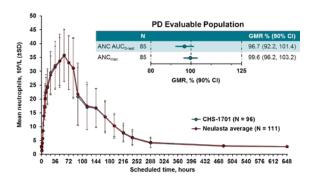
- European Commission approval received on September 25, 2018
- U.S. FDA action date anticipated by November 3, 2018

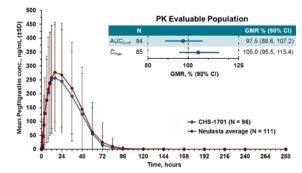


# UDENYCA™ is clinically differentiated with positive PK/PD and immunogenicity studies in over 600 healthy subjects

- Coherus successfully executed a 3-arm triplecrossover study in healthy volunteers. This study met bioequivalence with respect to PK and PD criteria, exceeding requirements
- We have focused on key regulatory clinical immunogenicity concerns, exposing ~450 healthy volunteers to UDENYCA™ in studies comprising more than 600 healthy subjects all together
- Based on the study results, we believe we have an industry-leading, highly robust clinical data package

## Results of UDENYCA™ triple-crossover PK/PD bioequivalence study





## UNDENYCA<sup>™</sup> Pegfilgrastim Biosimilar: Good Market Positioning and Favorable Characteristics

## Favorable Market Characteristics

- Opportunity for rapid adoption and high penetration in key segments
- Favorable reimbursement in 340B hospitals
- Favorable unique J-CODE allows control of ASP

## Strong Market Positioning

- High quality clinical package
- U.S. manufacturing
- Experienced commercial leadership, dedicated sales team in place

## Limited Competitive Set

- Pegfilgrastim biosimilar development appears challenging
- Multiple clinical and regulatory failures in the U.S. and E.U.

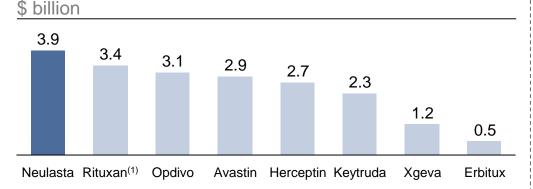
## Large Originator Market

- Neulasta sells ~\$4 billion per year in the U.S.
- ~\$5 billion worldwide



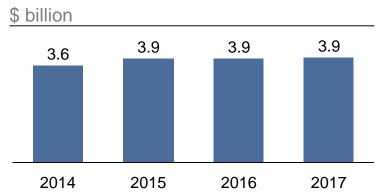
### Neulasta Is the Top-selling Oncology Biologic in the U.S.

#### Top oncology biologic drugs by sales in the U.S. in 2017

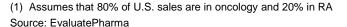


Neulasta is a cornerstone of cancer care,
mainstay treatment to prevent febrile
neutropenia and enable the delivery of cytotoxic
chemotherapy

#### **Neulasta Historical Revenues in the U.S.**



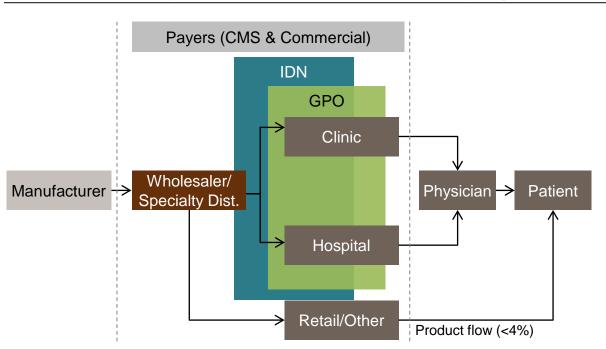
 U.S. Neulasta revenues stable at ~\$4 billion





### **Concentrated Market and Direct Buying Process**

#### Schematic of key stakeholders in Neulasta buying process



- Highly concentrated market, with >80% of Neulasta sales managed by roughly:
  - 2,000 clinics and hospitals
  - 400 IDNs/Corporations
  - 7 GPOs
- Straightforward process with buying decisions taken largely by providers



### New J-code Rule: Biosimilar Players Now Control Own ASP

- Unique coding for each biosimilar results in an average selling price (ASP) calculation methodology, unique to each biosimilar's "brand"
- This substantially reduces reimbursement uncertainty for providers/prescribers

Originator (e.g., Neulasta)

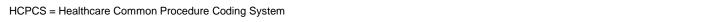
## Coding

- Each reference biologic has unique J-code associated with unique reported ASP
- Total Neulasta net sales / total Neulasta units each quarter

**ASP Methodology** 

Biosimilar (e.g., UDENYCA™)

- Each Biosimilar
   will receive unique
   HCPCS-code
   associated with
   unique reported
   ASP
- Total UDENYCA™
   net sales / total
   UDENYCA™ units
   each quarter



### Revised 340B Reimbursement Rule Favors Biosimilar Uptake in Hospitals

- The 340B Hospital segment represents ~29% of Neulasta U.S. Gross Sales
- The new CMS reimbursement rule in 340B considers biosimilars as "New and Innovative Technology"
- As such, biosimilars continue to be reimbursed at ASP <u>plus</u> 6% while originators are reimbursed at ASP <u>minus</u> 22.5%
- Biosimilars will receive this favorable reimbursement for 2-3 years, providing significant benefit to the hospital segment

### Incentives Aligned with Biosimilar Value Proposition



## Main Driver for Biosimilar Adoption



Standalone Oncology Clinics



- Cost recovery
- Outcomes



Hospital
Outpatient
Clinics



- 55%
- Acquisition cost
  - Cost recovery
  - Outcomes



Retail /
Mail
Services



Acquisition cost

- Health System under pressure to support new oncology treatment (e.g., immuno-oncology)
- Market incentivizing outcomes at lower costs (e.g., CMS' Oncology Care Model with ~25% of Neulasta share)
- Value drivers in these markets fundamentally aligned with UDENYCA™ value proposition

High Quality, Full Label, U.S. Manufacture



# Deep Understanding of Stakeholder' Roles and Incentives is Key to Support Successful Launch





**Leverage Point For Coherus** 

#### **Patient Journey**

## Evaluation / Diagnosis

Treatment Choice





#### **Description**

- Insurance status assessed
- Site-of-Care determined
- Dependent on Site-of-Care, insurance status and practice's standard "Pathway"
- Commercial patients are pre-authorized
- Choice usually at Practice discretion
- Establish parity coverage among Commercial Payers
- Influenced by Cost & Cost-Recovery
- Preference toward single brand
- Point of Product Support Services
- Nurse and patient audiences impacted at this point

#### **Decision Maker**





#### **Facilitator**





















# Sales Representatives Onboard to Address the UDENYCA™ Market Opportunity



- Seven regions and 67
   Oncology Account
   Managers aligned to
   market opportunity
- Training and onboarding ongoing
- Team sized to support vigorous launch



# **UDENYCA™** Aims to Deliver Comprehensive Value **Proposition**



**Brand** 

- Establish Coherus as a high quality, reliable biologic manufacturer
- Position UDENYCA™ as a "choice without compromise"



**Top-talent** 

 Hire top talent for Key Account, Sales & Market Access Teams (e.g., oncology, Buy & Bill)



Reliable supply

- In-market manufacturing (made in USA)
- Build sufficient inventory and capacity to exceed Demand forecast
- Establish supply & distribution chain preferred by market



Reimbursement Assistance Program

- Provider Reimbursement Services
- Patient Assistance Programs
- Patient Co-Pay Assistance



Coverage & coding

- Secure unique coding for launch
- Secure parity Payer coverage
- Establish transitional 340B Pass-Through Status for early 2019

# Development Hurdles Have Limited Pegfilgrastim U.S. Competitive Intensity

#### Filing status of selected players in the U.S.



- FDA CRL in October 2017
- Approved June 4, 2018



- FDA CRL in Jun 2016
- Announced refiling in 2019, after completing clinical studies



- Original BLA filed in 2014
- Status unknown

- Inherent drug properties lead to intra-patient variability confounding PK/PD, slowing down some players
- Relative immunogenicity to originator has emerged as a key regulatory issue to be addressed
- Manufacturing issues have also emerged as major hurdles

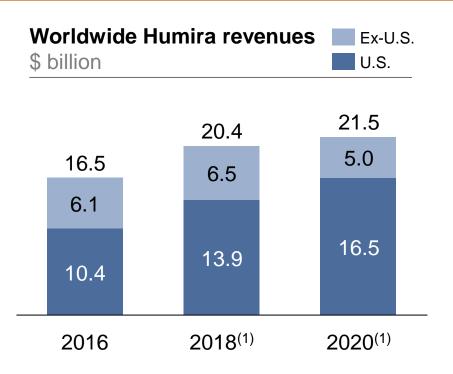


## Agenda

- Company Summary
- UDENYCA™ Pegfilgrastim Biosimilar
- Broad Unpartnered Pipeline



# CHS-1420 Adalimumab Biosimilar: Competitive Launch After Formulation IP Expiry/Invalidation



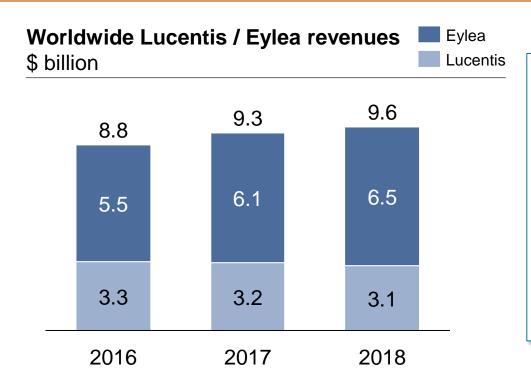
- Humira opportunity expected to be >\$20B globally and >\$15B in the U.S. by 2020
- CHS-1420 program focused on securing a competitive launch after expiration of formulation patents (Aug '22), or earlier invalidation
- BLA filing consistent with launch projection
- Coherus expects to launch leveraging own commercial infrastructure

(1) Projected

Source: Evaluate Pharma, IMS MIDAS



# CHS-3351 Lucentis and CHS-2020 Eylea Biosimilars: Large Follow-On Ophthalmology Opportunity



- Large and growing global market for retinal disorders (~\$10 billion)
- CHS-3351 ranibizumab (Lucentis) biosimilar initiating clinical development in 2018
- CHS-2020 aflibercept (Eylea) biosimilar initiated preclinical development



# CHS-131 with Potential to Address Significant Medical Needs in Metabolic Indications

#### Rationale for Metabolic Indications, NASH

- First in class selective modulator of PPAR γ
- Relevant in diseases involving insulin resistance and loss of mature, functional adipocytes with reduced adiponectin levels (NASH, lipodystrophy)
- PPARγ involved in gene activation and signaling pathways in differentiation of adipocytes
- Unlike the TZDs, CHS-131 has unique scaffold, does not promote adipogenesis in models
- CHS-131 increased adiponectin in healthy volunteers and diabetic patients
- CHS-131 demonstrated efficacy in Type 2 Diabetes Mellitus with differentiated safety profile

#### Commercial, Legal, Regulatory

- Significant unmet patient need in NASH
  - Very large and growing prevalent population
  - Significant burden of illness
  - No FDA approved therapies
  - Insulin resistance is a key disease driver
- Robust IP estate including patents and applications covering:
  - API
  - Formulations
  - Methods of treating NASH
- Phase 3 ready toxicology package



## Delivering on the Potential of the Platform and Laying the Foundation for Continued Growth

#### **Delivering on the Platform**

- ✓ Delivering on UDENYCA™
  - Approved in E.U.
  - BLA resubmitted to FDA in early May
     2018 approval tracking to
     November 2018 BSUFA date
  - U.S. launch preparations underway.
     Commercial and Sales team in place.
- ✓ CHS-1420 BLA preparation underway, expected launch in H2 2022
- ✓ Ophthalmology pipeline advancing;
   CHS-3351 Lucentis biosimilar, CHS-2020
   Eylea biosimilar

#### **Long-term Value Creation**

- ✓ UDENYCA™ well positioned in \$4 billion U.S. Neulasta market; supply chain and commercial plan in place
- ✓ Pipeline advancing with several potential product launches over five year horizon
- ✓ Financial plan supports long-term vision
- ✓ CHS-131 with positive safety data and potential in neurologic and metabolic indications



## Coherus BioSciences

2018 CANTOR GLOBAL HEALTHCARE CONFERENCE OCTOBER 2, 2018

