## Coherus BioSciences

August 2021



### **Forward Looking Statements**

Except for the historical information contained herein, the matters set forth in this primer are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, the risk that the parties are unable to obtain clearance under the Hart-Scott Rodino Antitrust Improvements Act, from the Committee on Foreign Investment in the United States, or any other statute or regulatory agency having jurisdiction with respect to the proposed transactions; our ability to advance toripalimab and other product candidates through development and registration, as well as the potential timing for regulatory filings, data readouts and other milestones or catalysts; our ability to develop toripalimab for the treatment of nasopharyngeal carcinoma or other indications; and our ability to successfully commercialize toripalimab and other products in the future; our ability to develop toripalimab as a combination therapy; Coherus' ability to successfully apply its capabilities developed for the oncology environment to the checkpoint inhibitor market or to establish toripalimab's position in the United States and Canadian markets; Coherus' ability to successfully compete against entrenched large competitors in the oncology and checkpoint inhibitor markets; the completion of ongoing pivotal clinical trials evaluating toripalimab; Coherus' ability to facilitate the first BLA filing for toripalimab with the FDA for nasopharyngeal carcinoma during 2021, and additional BLAs through 2023; and Coherus' 2021 and 2022 projected milestones. 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 caused by the COVID-19 pandemic; the risks and uncertainties inherent with commercialization; the risks and uncertainties of the clinical development and regulatory approval process, including (but not limited to) 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; risks and uncertainties in executing collaboration agreements and other joint ventures; and the risks and uncertainties of possible patent litigation. All forward-looking statements contained in this press release 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 months and nine months ended June 30, 2021, filed with the Securities and Exchange Commission on August 5, 2021 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter ended June 30, 2021 are not necessarily indicative of our operating results for any future periods.



## Agenda

- Introduction to Coherus Immuno-Oncology Strategy and Toripalimab
- Recap JUPITER-02 ASCO Plenary Presentation
- Toripalimab Development Program
- Long-term Immuno-oncology Strategy
- Strategic Roadmap Building on Biosimilars' Success





## Expanding Our Mission to Immuno-oncology



Building on our success with UDENYCA®, we are now expanding our pipeline to immuno-oncology with Junshi BioSciences' novel anti-PD-1 antibody, toripalimab.

Coherus is dedicated to expanding patient access to important medicines and delivering significant savings to the U.S. healthcare system.

# Transformational strategic alliance launches Coherus into rapidly growing immuno-oncology market

- Coherus acquired U.S., Canada rights to anti-PD-1 antibody toripalimab
- Complementary strengths: Junshi Biosciences' R&D capabilities and Coherus' U.S. commercial expertise
- Rolling BLA filing for recurrent/metastatic nasopharyngeal carcinoma (NPC) expected to be completed in 3Q 2021
- Potential for multiple additional toripalimab BLAs in next three years, including for lung cancer
- Long-term growth potential through PD-1 combinations including with Junshi Biosciences' TIGIT, eIL-2, and other molecules







# Torpalimab pivotal development program spans 19 studies across 12 tumor types

		Dose Escalation/Expansion	n Pivotal			
Organ Group	Indication	(Phase 1 / Phase 2)	(Phase 2 / Phase 3)	<b>BLA Submision</b>	Approved/Marketed*	Notes
Head and Neck	Nasopharyngeal carcinoma (3L, mono)			<b>—</b>		Rolling BLA submission; FDA Breakthrough Therapy Designati
	Nasopharyngeal carcinoma (1L, combo with chemo)			<b>→</b>		Data presented at ASCO 2021
Lung	EGFR negative NSCLC (1L, combo with chemo)			<b>→</b>		Met PFS primary endpoint in Interim Analysis
	EGFR mutated TKI failed NSCLC (combo with chemo)		<del></del>			
	NSCLC (neoadjuvant)		<b>—</b>			
	SCLC (1L, combo with chemo)		<b>—</b>			
Breast	TNBC (combo with albumin-bound paclitaxel)		<b>—</b>			
Gastrointestinal	ESCC (1L, combo with chemo)		<b>—</b>			Met PFS and OS primary endpoints in Interim Analysis
	ESCC (neoadjuvant)		<b>—</b>			
	HCC (1L, combo with lenvatinib)		<b>—</b>			
Gustromtestma	HCC (1L, combo with bevacizumab)		<b>—</b>			
	HCC (adjuvant)		<del></del>			
	Gastric carcinoma (3L, mono)					
Genitourinary	Urothelial carcinoma (2L, mono)		<b>—</b>			Approved in China
	Urothelial carcinoma (1L, PD-L1+)		<b>—</b>			
	Renal cell carcinoma (1L, combo with axitinib)		<b>—</b>			
Skin	Melanoma (2L, mono)			<b>→</b>		Approved in China
	Melanoma (1L, mono)		<b>—</b>			
	Mucosal melanoma (combo with axitinib)		<u> </u>			FDA Orphan Drug Designation
Multiple	Soft Tissue Sarcoma		<u> </u>			FDA Orphan Drug Designation

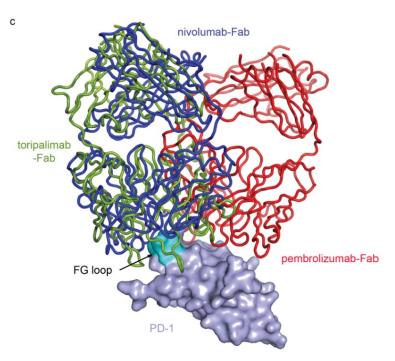
Potential for multiple additional toripalimab BLAs including lung cancer



# Toripalimab receptor binding optimized during design phase for unique domain interaction



### Comparative binding of PD-1 targeting mAbs



- Toripalimab (JS001): recombinant humanized anti-PD-1 monoclonal antibody
  - IP: IgG4/Kappa (CN104250302B) (PCT: WO2014/206107A1)
- Optimized during discovery and early development with unique CDR sequences and binding domains: PD-1 FG loop

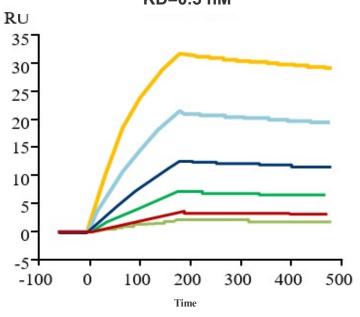
Source: Glycosylation-independent binding of monoclonal antibody toripalimab to FG loop of PD-1 for tumor immune checkpoint therapy." Liu H. et al. mAbs 11(4):681-690. doi: 10.1080/19420862.2019.1596513. Epub 2019 Apr 19







### **Toripalimab binding affinity** KD=0.3 nM



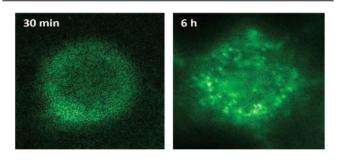
- The binding affinity of JS001 for PD-1 is about 0.3 nm as measured by Biacore T200
- This high binding affinity enables JS001 to bind more firmly to the PD-1 receptors on Tcells and better prevent the binding between PD-1 and PD-L1/PD-L2 on tumor cells



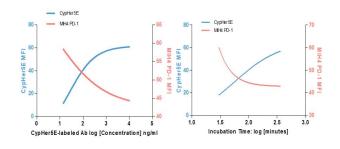
# Toripalimab demonstrates strong PD-1 receptor internalization induction



### Immunofluorescence assay



### Flow cytometry



- Upon binding with the PD-1 receptor, JS001 blocks
  the interaction of PD-1 with PD-L1 and PD-L2 and
  simultaneously induces the internalization of the
  PD-1 receptor, thereby decreasing the expression of
  PD-1 on the surface of the cell membrane
- Flow cytometry shows decrease in PD-1 expression on the cell surface during internalization of JS001 by simultaneously staining the JS001 non-competitive anti-PD-1 monoclonal antibody (clone MIH4)
- A decrease in PD-1 expression can improve the reactivity of T-cells to the antigen. This mechanism does not rely on PD-1 ligand (PD-L1) expression



## Agenda

- Introduction to Coherus Immuno-Oncology Strategy and Toripalimab
- Recap JUPITER-02 ASCO Plenary Presentation
- Toripalimab Development Program
- Long-term Immuno-oncology Strategy
- Strategic Roadmap Building on Biosimilars' Success





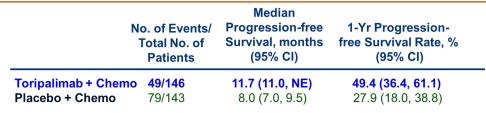
### **JUPITER-02:**

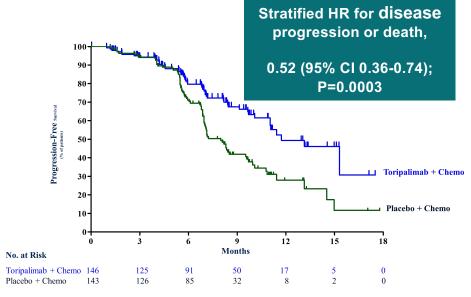
The randomized, double-blind, phase 3 study of toripalimab or placebo plus cisplatin and gemcitabine as first-line treatment for recurrent or metastatic nasopharyngeal carcinoma (NPC)

Rui-Hua Xu, MD, PhD
Sun Yat-Sen University Cancer Center, China
May 28, 2021



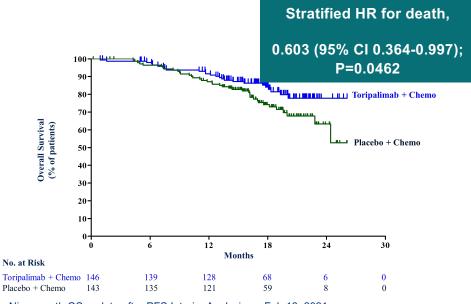
# Progression-Free Survival by BIRC per RECIST v1.1 and Preliminary Overall Survival





Interim Analysis Data cut-off Date: May 30, 2020

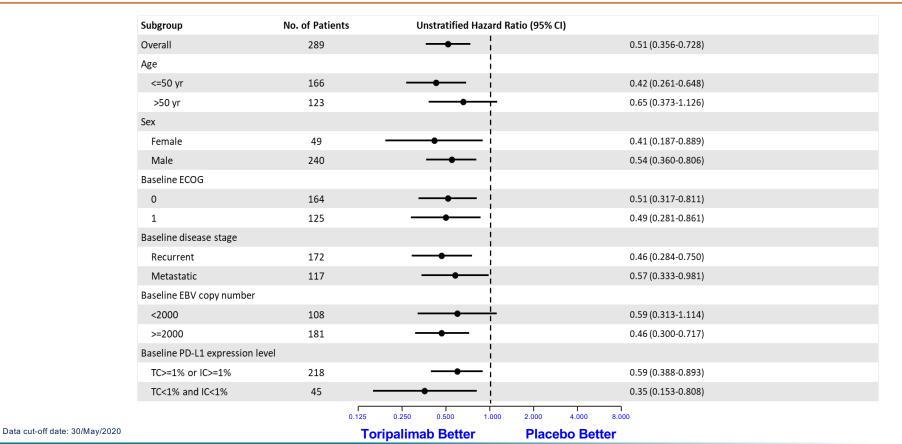




Nine-month OS update after PFS Interim Analysis on Feb 18, 2021



## **Progression Free Survival by BIRC in Key Subgroups**





## Response and Duration of Response by BIRC per RECIST v1.1

Characteristic (%)	Toripalimab + GP (N=146)	Placebo + GP (N=143)		
Objective Response Rate <sup>a</sup>	77.4	66.4		
95% CI	(69.8, 83.9)	(58.1, 74.1)		
P value	0.0335			
Best Overall Response a				
Complete Response	19.2	11.2		
Partial Response	58.2	55.2		
Stable Disease	10.3	13.3		
Progressive Disease	3.4	5.6		
Not evaluable	6.2	5.6		
Non-CR/non-PD <sup>b</sup>	2.7	8.4		
No evidence of disease <sup>c</sup>	0	0.7		
Median DoR, (95%CI), months	10.0 (8.8, NE)	5.7 (5.4, 6.8)		
HR (95%CI)	0.50 (0.3	33-0.78)		
P value	0.0014			



## **Treatment Emergent Adverse Events (TEAEs)**

Patients <sup>a</sup> , n (%)	Toripalim (N=1		Placebo + GP (N=143)	
	Any grade	Grade≥3	Any grade	Grade≥3
Any AEs	146 (100.0)	130 (89.0)	143 (100.0)	128 (89.5)
AEs related to study drug <sup>b,c</sup>	139 (95.2)	118 (80.8)	139 (97.2)	119 (83.2)
Immune-related AEs <sup>c</sup>	58 (39.7)	11 (7.5)	27 (18.9)	1 (0.7)
AEs leading to discontinuation	11 (7.5)	10 (6.8)	7 (4.9)	5 (3.5)
Infusion reactions	6 (4.1)	0	6 (4.2)	0
Fatal AEs	4 (2.7)	4 (2.7)	4 (2.8)	4 (2.8)
Incidence ≥ 30%				
Leukopenia	133 (91.1)	90 (61.6)	135 (94.4)	83 (58.0)
Anemia	129 (88.4)	69 (47.3)	135 (94.4)	57 (39.9)
Neutropenia	125 (85.6)	84 (57.5)	133 (93.0)	91 (63.6)
Nausea	101 (69.2)	2 (1.4)	119 (83.2)	4 (2.8)
Vomiting	98 (67.1)	3 (2.1)	94 (65.7)	3 (2.1)
Thrombocytopenia	93 (63.0)	48 (32.9)	89 (62.2)	41 (28.7)
Decreased appetite	78 (53.4)	1 (0.7)	84 (58.7)	0 (0)
Constipation	57 (39.0)	0 (0)	64 (44.8)	0 (0)
Aspartate aminotransferase increased	55 (37.7)	2 (1.4)	44 (30.8)	2 (1.4)
Alanine aminotransferase increased	53 (36.3)	1 (0.7)	57 (39.9)	0 (0)
Fatigue	52 (35.6)	2 (1.4)	51 (35.7)	3 (2.1)
Pyrexia	45 (30.8)	2 (1.4)	31 (21.7)	1 (0.7)
Hypothyroidism	45 (30.8)	0 (0)	24 (16.8)	0 (0)
Neuropathy peripheral	44 (30.1)	0 (0)	41 (28.7)	1 (0.7)
Diarrhea	44 (30.1)	3 (2.1)	33 (23.1)	0 (0)
Hyponatremia	37 (25.3)	13 (8.9)	52 (36.4)	6 (4.2)



### **Jupiter-02 study conclusions**

- JUPITER-02 is the first international Phase III trial to prove the addition of toripalimab to GP as a first-line treatment for R/M NPC patients provided superior PFS, OS than GP alone.
  - Significant improvement in PFS: mPFS 11.7 vs. 8.0 months, HR=0.52 (95%CI: 0.36-0.74), p=0.0003
  - Although mOS was not mature in either arm, a 40% reduction in risk of death was observed in the toripalimab arm over the placebo arm.
  - A second interim OS analysis will be performed at pre-specified final PFS analysis followed by the final OS analysis.
- No new safety signals were identified with toripalimab added to GP.
- Toripalimab plus GP represents a new standard of care as 1<sup>st</sup> line therapy for patients with R/M NPC.

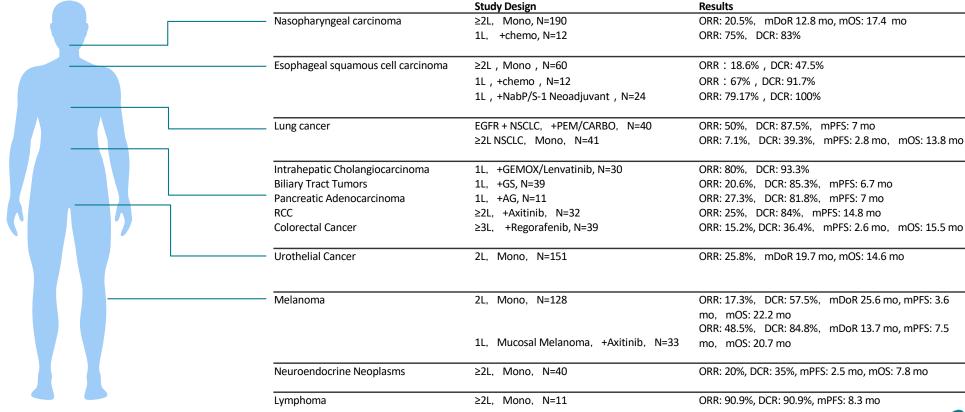


## Agenda

- Introduction to Coherus Immuno-Oncology Strategy and Toripalimab
- Recap JUPITER-02 ASCO Plenary Presentation
- Toripalimab Development Program
- Long-term Immuno-oncology Strategy
- Strategic Roadmap Building on Biosimilars' Success



# Toripalimab has demonstrated anti-tumor activity across multiple tumor types both as monotherapy and in combination





## Comprehensive toripalimab pivotal development program

## Adjuvant / Neoadjuvant

HCC Adjuvant JUPITER-04 P3 Mono vs placebo

NSCLC Neoadjuvant JUPITER-09 P3 Mono vs placebo

ESCC Neoadjuvant Combo vs chemo

### **First Line**

NSCLC EGFR(-) JUPITER-03 P3 Chemo combo vs chemo

NSCLC EGFR(+) JUPITER-07 P3 Chemo combo vs chemo

TNBC JUPITER-05 P3 Chemo combo vs chemo

SCLC JUPITER-08 P3 Chemo combo vs chemo

RCC
JUPITER-12 P3
Combo w axitinib vs sunitinib

UC PD-L1+ Chemo combo vs chemo Melanoma

JUPITER-01 P3 Mono vs dacarbazine

NPC JUPITER-02 P3 Chemo combo vs chemo

EC JUPITER-06 P3 Chemo combo vs chemo

HCC JUPITER-10 P3 Combo w bevacizumab vs sorafenib

HCC JUPITER-11 P3 Combo w lenvatinib vs lenvatinib

Mucosal Melanoma P3 Combo with axitinib vs pembrolizumab

### ≥2<sup>nd</sup> Line

Melanoma POLARIS01 P2 Mono single arm

NPC POLARIS02 P2 Mono single arm

UC POLARIS03 P2 Mono single arm

GC POLARIS04 P2 Mono single arm



## Four toripalimab pivotal trials in lung cancer

### **NSCLC** (1L, chemo combo)

Total enrollment: 465 patients

Primary Endpoint: PFS

Key Sec. Endpoints: OS, ORR

### Status:

Dec 2020: Met primary PFS endpoint at interim analysis Data to be presented

at WCLC Sept. 2021

### EGFR mutated TKI failed NSCLC (1L, chemo combo)

Total enrollment: 350 patients

Primary Endpoint: PFS

Key Sec. Endpoints: OS, ORR

#### Status:

Enrollment completion expected by year end Data expected in 2022

### **NSCLC** (neoadjuvant)

Total enrollment: 406 patients

Primary Endpoint: mPR

Key Sec. Endpoints: EFS

### Status:

Enrollment completion expected by year end Data expected in 2022

### SCLC (1L, chemo combo)

Total enrollment: 420 patients

Primary Endpoint: PFS, OS

Key Sec. Endpoints: ORR

### Status:

Enrollment complete
Data expected in 2022



# Toripalimab studies with data through 2022 ESCC, TNBC and HCC

### ESCC (1L, chemo combo)

Total enrollment: 500 patients

Primary Endpoint: PFS, OS

Key Sec. Endpoints: ORR

#### Status:

Feb 2021: Met primary PFS and OS endpoints at interim analysis

Data to be presented

at ESMO Sept. 2021

### TNBC (1L, chemo combo)

Total enrollment: 660 patients

Primary Endpoint: PFS

Key Sec. Endpoints: OS, ORR

### Status:

Enrollment completion expected by year end Data expected in 2022

### **HCC** (adjuvant)

Total enrollment: 402 patients

Primary Endpoint: RFS

Key Sec. Endpoints: TTR, OS

### Status:

Enrollment completion expected by year end Data expected in 2022

### HCC (1L, lenvatinib combo)

Total enrollment: 519 patients

Primary Endpoint: PFS, OS

Key Sec. Endpoints: ORR

### Status:

Enrollment completion expected by year end Data expected in 2022



# Update following 3Q 2021 FDA meeting: 1L NPC indication to be filed concurrently with 2L/3L BLA

Recurrent / Metastatic Nasopharyngeal Carcinoma (RM-NPC)

- Following a recent meeting with FDA, Junshi Biosciences plans to submit the BLA for toripalimab for 1L treatment of RM-NPC concurrently with the BLA for 2L/3L RM-NPC
- Rolling BLA submission expected to be completed later this quarter.



## Agenda

- Introduction to Coherus Immuno-Oncology Strategy and Toripalimab
- Recap JUPITER-02 ASCO Plenary Presentation
- Toripalimab Development Program
- Long-term Immuno-oncology Strategy
- Strategic Roadmap Building on Biosimilars' Success



# Long-term strategy includes both fast-follower and transformative assets synergistic with toripalimab

### PD-1 "Backbone"

- File and launch NPC
- Expand monotherapy label in lung, other
- Establish partnerships with 3<sup>rd</sup> parties to drive toripalimab utilization

### **Fast-Follower**

- Evaluate and partner Junshi assets (options and ROFN)
- Co-formulate to create LCM "super brand"
- Internal pipeline or selective in-licensing

### **Transformational**

- Seek opportunities to step-change cancer care (TME, myeloid cells, T-Cell priming expansion)
- Internal pipeline or selective in-licensing

**Toripalimab** 

TIGIT elL-2

Novel I-O Agents

Tissue and Indication-focused



# Options and ROFNs in the Coherus-Junshi collaboration provide fast-follower opportunities

Options to two clinically validated targets

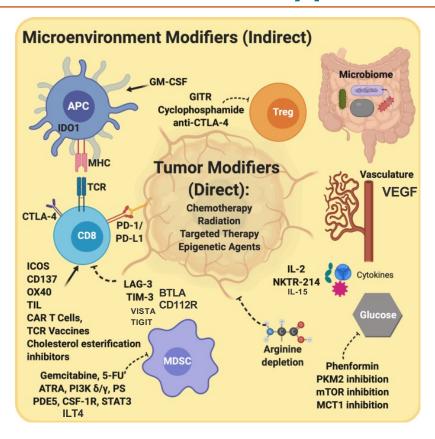
- JS006, Anti-TIGIT Immune inhibitory checkpoint that limits anti-tumor response. Demonstrated synergy in combination with anti-PD(L)1. Currently in Phase 1 clinical development.
- JS018, Engineered IL-2 Cytokine that helps effector T cells proliferate and expand for more efficient killing of target tumor cells

Certain negotiation rights to two additional targets

- Clinically validated target that works synergistically with PD-1 in the activation and augmentation of anti-tumor immunity
- Novel immune inhibitory molecule closely related to TIGIT that can independently inhibit the anti-tumor immune response



## Beyond PD-1 and fast follower combinations: Transformational approaches in the tumor micro-environment



- Enhancing antigen presentation and T-cell priming
- Enhancing T-cell migration and infiltration into the tumor
- Expansion of T Cells through cytokines
- Overcoming T Cell exhaustion with immune checkpoint blockade
- Inhibiting T Reg activity, preferentially in the TME
- Inhibiting myeloid cell mediated immune suppression in the TME



## Agenda

- Introduction to Coherus Immuno-Oncology Strategy and Toripalimab
- Recap JUPITER-02 ASCO Plenary Presentation
- Toripalimab Development Program
- Long-term Immuno-oncology Strategy
- Leveraging Biosimilars Capabilities



## Coherus 2.0: Investing cash generated by commercial biosimilar business into immuno-oncology

### **Existing Capabilities**

- Analytical & Process
- Clinical-Regulatory
- Commercial Excellence



### Biosimilar cash flows

 Fuel for investments in high growth areas



- Proven MOA
- Promising combinations
- Large growing market



# Immuno-oncology investment directly leverages Coherus capabilities



**Analytical and Process Sciences** 

Foundational capabilities to identify and develop best in class antibodies

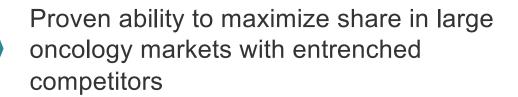


Clinical and Regulatory Expertise

Track record of executing in oncology and success with US FDA



Commercial Excellence





# **UDENYCA®** success demonstrates Coherus commercial capabilities



Relationships

**Distribution** 

Access

**Branded Value** 



Deeply experienced commercial and medical team deployed across the U.S.



Trusted relationships and thorough knowledge of providers, payers, and GPO accounts across buy & bill marketplace

Best-in-class patient and provider services



Trusted product and supply

Proven pricing and contracting capabilities



# Commercial team with deep oncology relationships and years of industry experience



- 67 oncology account managers with an average of ~20 years in pharmaceutical sales and ~10 years in oncology sales
- Estimated ~45k-50k account interactions per year

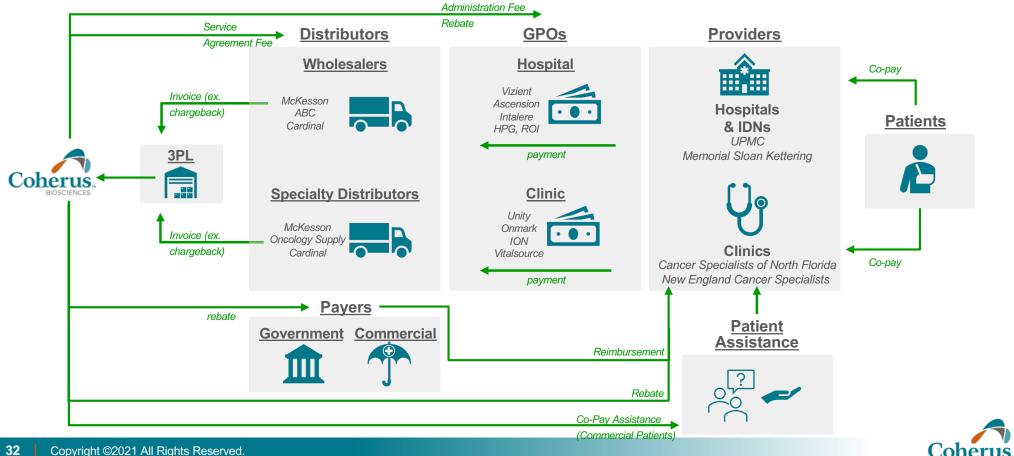
Territory	Regional Manager Oncology Sales Experience		
West	18 years		
North Central	7 years		
South Central	19 years		
Great Lakes	8 years		
North-East	29 years		
Mid-Atlantic	12 years		
South-East	12 years		







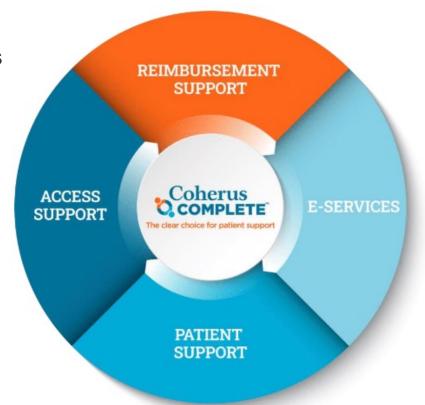
## Mastery of the complex U.S. Buy & Bill market ecosystem delivered results



## Coherus Complete™ Best in class patient support programs

Reimbursement support provided by patient access specialists

Field reimbursement managers assist to streamline patient access



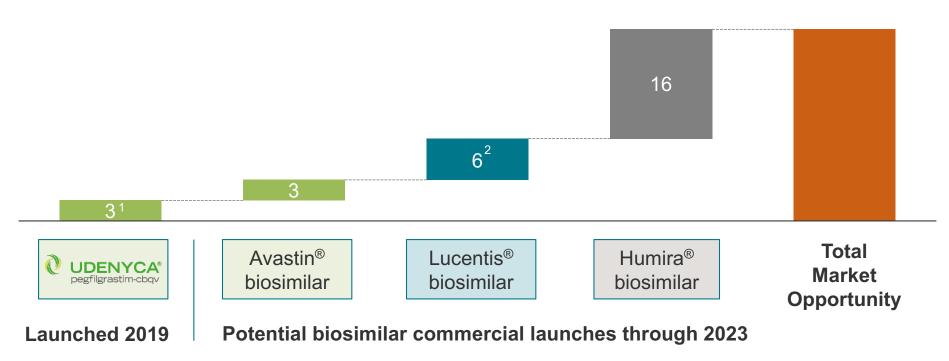
Patient support through financial assistance programs

New E-services to streamline patient access



# \$28 billion market opportunity provides strong cash generation potential for biosimilars portfolio

U.S. Market Opportunity, total revenues in 2020 in U.S. \$ billion



1 Total 2020 U.S. revenues for pegfilgrastim products

2 Assumed addressable market opportunity is entire U.S. anti-VGEF ophthalmology market



Source: Evaluate Pharma

# Accelerating pipeline progress to deliver data and regulatory catalysts over the next 18 months



√CHS-201 BLA submitted

Completion of rolling BLA submission for RM-NPC

Clinical data: 1L NSCLC at WCLC, 1L ESCC at ESMO CHS-1420 BsUFA target date December 2021

Coherus Analyst Day Potential toripalimab approval, RM-NPC

Clinical data:
1L SCLC,
Neoadj. NSCLC,
NSCLC EGFR + TKI -,
1L TNBC,
HCC adjuvant,
1L HCC,
JS006 Anti-TIGIT

Potential CHS-201 approval, CHS-305 BLA filing<sup>2</sup>



<sup>1</sup> Submission by partner Bioeq expected mid 2021

<sup>2</sup> Pending successful completion of 3-way pharmacokinetics study

## Coherus BioSciences

