

# Coherus Highlights Anticipated New Product Launches and Immuno-oncology Growth Strategy at Analyst Day Event

Mar 29, 2022

— Multiple near-term anticipated product launches and development of innovative immuno-oncology pipeline position Coherus for long-term growth –

— Introducing 2026 revenue target o \$1.2 billion in annual net sales from Coherus' diversified product portfolio –

REDWOOD CITY, Calif., March 29, 2022 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS), beginning at 9:30 a.m. Eastern Daylight Time today, is hosting a meeting with analysts and investors to present the Company's corporate strategy to build a leading innovative immuno-oncology ("I-O") franchise funded with cash generated through net sales of its diversified portfolio of FDA-approved therapeutics. A simultaneous webcast and slides for the meeting are available on the <a href="Events and Presentations page">Events and Presentations page</a> of the Coherus website.

"Executing on our strategy, by 2026 we believe that our commercial product portfolio will generate more than \$1.2 billion in annual net sales and that our R&D productivity will position Coherus as a new leader in immuno-oncology," said Denny Lanfear, CEO of Coherus. "We believe having proprietary rights to a well-developed and commercialized PD-1 is required for long-term success in immuno-oncology, especially for companies developing PD-1 combinations who wish to earn label claims and commercialize them. Our foundational I-O asset, toripalimab, is an efficacious and differentiated PD-1 inhibitor developing a consistently strong clinical profile in studies across multiple tumor types. If approved, toripalimab will provide our commercial point of entry into the rapidly growing checkpoint inhibitor and PD-1 combination market. For the first time, today we are providing details of our PD-1 combination programs, including our clinical-stage anti-TIGIT antibody candidate and our internal preclinical programs targeting immune-suppressive mechanisms in the tumor microenvironment."

Lanfear added, "We believe that we will successfully execute on both our near-term product launches and our innovative immuno-oncology pipeline development to position Coherus for long-term growth and significant shareholder value creation over our planning period."

#### Immuno-Oncology R&D Update: Positioned for Growth Across a Broad Portfolio

At the meeting, Theresa LaVallee, PhD, Chief Development Officer, is providing an update on the Company's clinical stage immuno-oncology R&D programs. Toripalimab was granted Breakthrough Therapy designation in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC in 2021 as well as in monotherapy in the second or third-line treatment of recurrent or metastatic NPC, and a Biologics License Application ("BLA") for these indications is currently under priority review by the United States Food and Drug Administration ("FDA") with a Prescription Drug User Fee Act target action date of April 30, 2022. Coherus and partner Junshi Biosciences are working closely with the FDA to complete the review process including the scheduling of any required inspections in China. Dr. LaVallee is also presenting details about the potential to pursue additional indications for toripalimab, including through possible expansion of several ongoing pivotal studies into multi-regional clinical trials with enrollment of patients in the United States.

Dr. LaVallee and Dr. Sanjay Khare, Senior Vice President of Immuno-oncology R&D, are presenting, for the first time, an overview of Coherus' earlier stage immuno-oncology R&D programs:

- CHS-006 (anti-TIGIT antibody) is being evaluated in an ongoing clinical trial. In 2023, Coherus expects to receive clinical
  data informing dose-selection and is planning to enroll new patient cohorts in the United States to evaluate CHS-006 +
  toripalimab for treatment of several solid tumor indications that may include non-small cell lung cancer, small cell lung
  cancer, esophageal cancer, and hepatocellular carcinoma.
- Coherus is pursuing two early-stage development candidates designed to improve anti-PD-1 clinical benefit by transforming an unfavorable tumor microenvironment ("TME") to a more favorable TME. Coherus expects to file investigational new drug ("IND") applications with the FDA in 2023 for CHS-1000, an antibody targeting ILT4, and in 2024 for CHS-3318, an antibody targeting CCR8.

Coherus expects its immuno-oncology R&D investments will lead to ongoing identification of promising pipeline assets and the submission of at least one new IND application for immuno-oncology development candidates per year beginning in 2023.

#### Commercial Update: Preparing to launch as many as four new products through mid-2023

Paul Reider, Chief Commercial Officer, is presenting an overview of the Company's plans for up to four new product launches in the next 15 months.

- Toripalimab launch readiness is on track and will benefit from the high overlap in customer accounts between UDENYCA® and toripalimab. If approved, toripalimab will be the first and only PD-1 inhibitor registered in the United States for the treatment of advanced nasopharyngeal carcinoma.
- CIMERLI<sup>TM</sup> (ranibizumab-ranq), a Lucentis<sup>®</sup> biosimilar, is under FDA review with a target action date of August 2, 2022. If approved, Coherus is preparing to launch CIMERLI<sup>TM</sup> in the second half of 2022 into the \$8B anti VEGF market and to drive adoption among retina specialists that the Company believes will be receptive to using an anti-VEGF biosimilar.
- The FDA approved Coherus' Humira <sup>®</sup> biosimilar, YUSIMRY<sup>TM</sup> (adalimumab-aqvh), in December 2021, and Coherus plans to launch YUSIMRY<sup>TM</sup> in the United States on or after July 1, 2023. With projected 2022 U.S. Humira<sup>®</sup> net sales of more than \$18 billion, the Humira<sup>®</sup> market represents a uniquely large and attractive opportunity. Coherus has made significant investments in manufacturing capacity and expects to be a low-cost, high-volume adalimumab manufacturer. Coherus

expects this investment to result in launch-year manufacturing capacity of approximately 1.2 million units, or about 10% of the overall adalimumab market, equal to the Company's target market share. After additional YUSIMRY <sup>TM</sup> scale-up efforts, the current manufacturing site has the potential to supply as much as 30% of the overall U.S. adalimumab market, three times Coherus' target market share.

Coherus is planning a potential 2023 launch, assuming approval by the FDA, of its UDENYCA<sup>®</sup> (pegfilgrastim-cbqv) on-body injector ("OBI") presentation. The UDENYCA<sup>®</sup> OBI would enable Coherus to compete directly against Neulasta<sup>®</sup> Onpro<sup>®</sup>, which has approximately a 50% share of the overall pegfilgrastim market. Coherus believes the on-body segment of the pegfilgrastim market represents a \$1 billion market opportunity and that a UDENYCA<sup>®</sup> OBI would generate significant new growth for the UDENYCA<sup>®</sup> franchise in 2023 and beyond.

#### Financial Update: Economies of scale within the Coherus business model

Chief Financial Officer, McDavid Stilwell, is presenting an overview of the Company's cost structure as well as a projected range of annual net sales for 2026.

Coherus projects combined R&D and SG&A expenses in 2022 to be in the range of \$415 million to \$450 million, excluding license fee and potential milestone payments to partner Junshi Biosciences. The projected increase in combined R&D and SG&A expenses compared to 2021 is driven primarily by costs the Company expects to incur with the anticipated launches of two new products, toripalimab and CIMERLI<sup>TM</sup>, as well as manufacturing and development costs for additional presentations of UDENYCA<sup>®</sup> and of YUSIMRY<sup>TM</sup>, which Coherus is planning to launch in 2023.

Since Coherus' commercial organization is already operating at scale, Coherus expects additional new product launches will largely leverage existing infrastructure, with some additional capabilities added to support launches outside of oncology. R&D expenses are expected to trend higher from 2024 through 2026 as Coherus initiates new clinical trials for CHS-006, CHS-1000 and CHS-3318. Full year 2026 operating expenses are expected to increase by only 15 to 25 percent compared to 2022 operating expenses.

Mr. Stilwell is also providing an estimate of the long-term revenue potential of the Company's diversified product portfolio, assuming all four new products are approved and launched, with a range for 2026 net sales of \$1.2 billion to \$2.2 billion.

#### **About Coherus BioSciences**

Coherus is a commercial stage biopharmaceutical company building a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. A biologics license application for toripalimab for the treatment of metastatic or recurrent nasopharyngeal carcinoma is currently under priority review by the FDA, with a target action date of April 2022. Toripalimab is also being evaluated in pivotal clinical trials for the treatment of cancers of the lung, breast, liver, skin, kidney, stomach, esophagus, and bladder.

Coherus markets UDENYCA<sup>®</sup> (pegfilgrastim-cbqv), a biosimilar of Neulasta<sup>®</sup> in the United States, and expects to launch the FDA-approved Humira<sup>®</sup> biosimilar YUSIMRY™ (adalimumab-aqvh) in the United States in 2023. The FDA is currently reviewing the biologics license application for CHS-201, a biosimilar of Lucentis<sup>®</sup> (ranibizumab), with a target action date of August 2022. Coherus is also developing CHS-305, a biosimilar of Avastin<sup>®</sup> (bevacizumab).

### **Forward-Looking Statements**

Except for the historical information contained herein, the matters set forth in this press release 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, statements regarding Coherus' ability to build its immuno-oncology franchise to achieve a leading market position; Coherus' ability to generate cash; Coherus' investment plans; Coherus' expectations for the launch date of YUSIMRY™ and other products; projections for manufacturing capacity, future revenues, R&D and other operating expenses, market sizes and market opportunities; expectations about the approval and launch of toripalimab; development plans for Coherus' early-stage product candidates; expectations regarding inspections in China; expectations about the efficacy of toripalimab; and expectations for multiple near-term product launches.

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; risks relating to the COVID-19 pandemic; risks related to our existing and potential collaboration partners; risks of the drug development position of Coherus' competitors; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review, international aspects of Coherus' business and the timing of Coherus' regulatory filings; the risk of FDA review issues; the risk of Coherus' execution of its change in strategy from a focus on biosimilars to a strategy using cash from its portfolio to fund an immuno-oncology franchise; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' drug candidates; and the risks and uncertainties of possible litigation. All forward-looking statements contained in this press release speak only as of the date of this press release. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the significant 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' Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on February 23, 2022, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission.

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