Coherus Launches YUSIMRY™, a Biosimilar of Humira®, at $995 per Carton in U.S.

–$995 per carton (two 40 mg/0.8 mL autoinjectors) represents a discount of more than 85% compared to Humira® –

– YUSIMRY™ meets high unmet need by providing patients, employers, physicians and payers with low-cost access to adalimumab treatment –

REDWOOD CITY, Calif., July 03, 2023 (GLOBE NEWSWIRE) -- **Coherus BioSciences, Inc.** (“Coherus”, Nasdaq: CHRS), today announced that YUSIMRY™ (adalimumab-aqvh) is now available for commercial sale in the United States at a list price of $995 per carton for two 40 mg/0.8 mL autoinjectors, representing a discount of more than 85% to Humira® (adalimumab), currently priced at $6,922 per carton of two pens.

“Adalimumab products are important medicines for the treatment of serious autoimmune diseases, but cost is a barrier for many patients. With the launch of YUSIMRY, patients are now able to choose and access a high-quality, safe, and effective treatment at significant savings compared to Humira,” said Denny Lanfear, Coherus’ Chairman and Chief Executive Officer. “The price of Humira is nearly $90,000 a year today, putting this important therapy out of reach for many patients who are experiencing difficult financial health challenges. Our price for YUSIMRY of less than $13,000 a year was enabled by our investment in robust large-scale manufacturing, allowing us to be a high-volume, low-cost adalimumab biosimilar producer, ensuring reliable supply, and passing the savings directly to patients in need.”

YUSIMRY is presented in a state-of-the-art autoinjector and includes Coherus’ proprietary non-stinging, citrate-free formulation and a 29-gauge needle. YUSIMRY, approved in 2021 by the United States Food and Drug Administration (“FDA”), is a tumor necrosis factor (“TNF”) blocker indicated to reduce the signs and symptoms of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, and ankylosing spondylitis, and to treat Crohn’s disease, ulcerative colitis, plaque psoriasis and hidradenitis suppurativa. YUSIMRY Solutions™- Coherus’ patient services platform – will ensure improved access and a fast and seamless experience as patients start or switch to YUSIMRY treatment based on a determination by their healthcare provider.

About YUSIMRY

YUSIMRY™ (adalimumab-aqvh), a biosimilar of Humira® (adalimumab), is a tumor necrosis factor (“TNF”) blocker indicated to reduce the signs and symptoms of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, and ankylosing spondylitis, and to treat Crohn’s disease, ulcerative colitis, plaque psoriasis and hidradenitis suppurativa.

IMPORTANT SAFETY INFORMATION AND INDICATIONS
YUSIMRY™ (adalimumab-aqvh) is biosimilar* to Humira® (adalimumab injection).

WARNING: SERIOUS INFECTIONS AND MALIGNANCY
See full prescribing information for complete boxed warning.
Patients treated with YUSIMRY are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue YUSIMRY if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before YUSIMRY use and during therapy. Initiate treatment for latent TB prior to YUSIMRY use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with YUSIMRY prior to initiating therapy in patients: 1. with chronic or recurrent infection; 2. who have been exposed to TB; 3. with a history of opportunistic infection; 4. who resided in or traveled in regions where mycoses are endemic; 5. with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with YUSIMRY, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

Do not start YUSIMRY during an active infection, including localized infections.

- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.
- Drug interactions with biologic products: A higher rate of serious infections has been observed in rheumatoid arthritis (RA) patients treated with rituximab who received subsequent treatment with a tumor necrosis factor (TNF) blocker. An

increased risk of serious infections has been seen with the combination of TNF blockers with anakinra or abatacept, with no demonstrated added benefit in patients with RA. Concomitant administration of YUSIMRY with other biologic disease-modifying antirheumatic drugs (DMARDs) (e.g., anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions as well as the lack of demonstrated benefit of such combinations.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including adalimumab. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including adalimumab. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

- Consider the risks and benefits of YUSIMRY treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among adalimumab-treated patients compared to control patients.
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for adalimumab-treated patients. Examine all patients, particularly those with a history of prolonged immunosuppressant or psoralen plus ultraviolet A light (PUVA) therapy, for the presence of NMSC prior to and during treatment with YUSIMRY.
- In adalimumab clinical trials, there was an approximate 3-fold higher rate of lymphoma than expected in the general U.S. population. Patients with chronic inflammatory diseases, particularly those with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at higher risk of lymphoma than the general population, even in the absence of TNF blockers.
- Postmarketing cases of acute and chronic leukemia were reported with TNF blocker use. Approximately half of the postmarketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents.

HYPERSENSITIVITY

- Anaphylaxis and angioneurotic edema have been reported following adalimumab administration. If a serious allergic reaction occurs, stop YUSIMRY and institute appropriate therapy.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including adalimumab, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy.
- Exercise caution in patients who are carriers of HBV and monitor them during and after YUSIMRY treatment.
- Discontinue YUSIMRY and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming YUSIMRY after HBV treatment.

NEUROLOGIC REACTIONS

- TNF blockers, including adalimumab, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, optic neuritis, and Guillain-Barré syndrome.
- Exercise caution when considering YUSIMRY for patients with these disorders; discontinuation of YUSIMRY should be considered if any of these disorders develop.
- There is a known association between intermediate uveitis and central demyelinating disorders.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with adalimumab.

- Consider stopping YUSIMRY if significant hematologic abnormalities occur.

CONGESTIVE HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) has been reported with TNF blockers. Cases of worsening CHF have been observed with adalimumab; exercise caution and monitor carefully.

AUTOIMMUNITY

- Treatment with YUSIMRY may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

- Patients on YUSIMRY should not receive live vaccines.
- Pediatric patients, if possible, should be brought up to date with all immunizations before initiating YUSIMRY therapy.
- Adalimumab is actively transferred across the placenta during the third trimester of pregnancy and may affect immune response in the in utero exposed infant. The safety of administering live or live-attenuated vaccines in infants exposed to YUSIMRY in utero is unknown. Risks and benefits should be considered prior to vaccinating (live or live-attenuated) exposed infants.

ADVERSE REACTIONS

- The most common adverse reactions in adalimumab clinical trials (>10%) were: infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash.

INDICATIONS

- **Rheumatoid Arthritis:** YUSIMRY is indicated, alone or in combination with methotrexate or other non-biologic DMARDs, for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis.
- **Juvenile Idiopathic Arthritis**: YUSIMRY is indicated, alone or in combination with methotrexate, for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.
- **Psoriatic Arthritis:** YUSIMRY is indicated, alone or in combination with non-biologic DMARDs, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis.
- **Ankylosing Spondylitis**: YUSIMRY is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.
- **Crohn's Disease:** YUSIMRY is indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- **Ulcerative Colitis:** YUSIMRY is indicated for the treatment of moderately to severely active ulcerative colitis in adult patients.
  Limitations of Use:
  The effectiveness of YUSIMRY has not been established in patients who have lost response to or were intolerant to TNF blockers.
- **Plaque Psoriasis:** YUSIMRY is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. YUSIMRY should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.
- **Hidradenitis Suppurativa:** YUSIMRY is indicated for the treatment of moderate to severe hidradenitis suppurativa in adult patients.

*Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of YUSIMRY has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

Click for YUSIMRY™ Full Prescribing Information, including Boxed Warning and Medication guide

About Coherus BioSciences
Coherus is a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of its diversified portfolio of FDA-approved therapeutics.

In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. The Biologics License Application for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma is currently under review by the FDA.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, CIMERLI® (ranibizumab-eqrn), a biosimilar of Lucentis®, and YUSIMRY™ (adalimumab-aqvh), a biosimilar of Humira®.

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 expectations for the future price of YUSIMRY™.

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, risks related to our existing and potential collaboration partners, the risks and uncertainties inherent in the clinical drug development process; risks of the drug development position of Coherus' competitors; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review, the risk of FDA review issues; 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' Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2023, filed with the Securities and Exchange Commission on May 8, 2023, including the section therein captioned "Risk Factors" and in other documents that Coherus files with the Securities and Exchange Commission.

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/34c5db37-10e4-460d-b799-803d209cdbbe

YUSIMRY™ (adalimumab-aqvh) product image

YUSIMRY™ (adalimumab-aqvh) - list price $995 per carton of two 40 mg/0.8 mL autoinjectors See https://www.yusimry.com for YUSIMRY™ Full

Prescribing Information, including Boxed Warning and Medication guide.

Source: Coherus BioSciences, Inc.