

Accord BioPharma, Inc. Announces Completion of UDENYCA® (pegfilgrastim-cbqv) Franchise Acquisition from Coherus BioSciences, Inc., Expanding U.S. Biosimilar Portfolio



NEWS PROVIDED BY
Accord BioPharma →
Apr 14, 2025, 08:30 ET

Finalization of acquisition reinforces Accord BioPharma and Intas' commitment to growth in the U.S. biosimilar market

RALEIGH, N.C., April 14, 2025 /PRNewswire/ -- **Accord BioPharma**, Inc., the U.S. specialty division of Intas Pharmaceuticals, Ltd., focused on the development of oncology, immunology, and critical care therapies, announced today that Intas Pharmaceuticals has completed its acquisition of the UDENYCA® (pegfilgrastim-cbqv) business from Coherus BioSciences, Inc. UDENYCA, a biosimilar to Neulasta® (pegfilgrastim), expands the company's portfolio of FDA-approved products and accelerates Accord BioPharma's growth in the biosimilar industry.

By acquiring UDENYCA, Accord BioPharma will continue to make this treatment available to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs. UDENYCA's three administration options — autoinjector (AI), on-body injector (OBI), and prefilled syringe (PFS) — offer flexibility for patients to receive their treatment at home, on-the-go, or in the office. Since the brand's commercial launch, more than 300,000 patients are estimated to have been treated with UDENYCA and over 1.4 million units have been sold.

The acquisition not only expands Accord BioPharma's product offerings, but also brings a wealth of talent from Coherus BioSciences. Key Coherus employees across multiple functions, including Sales, Marketing, Finance, Supply Chain, and Quality and Manufacturing, will join Accord BioPharma, playing a crucial role in supply and services continuity/transition and expanding the company's work around UDENYCA.

"The completion of the UDENYCA acquisition marks a pivotal moment for Accord BioPharma, as it not only strengthens our market presence but broadens our capabilities as we endeavor to innovate and expand in the biosimilar space," said Chrys Kokino, U.S. President of Accord. "We are delighted to welcome talented employees from Coherus, whose historical knowledge and expertise will complement that of our existing team, making us stronger and better equipped to achieve our goals with UDENYCA."

"We are energized by this addition to Accord BioPharma's portfolio because it exemplifies our commitment to improving patient access to high-quality treatments that effectively meet the needs of both patients and healthcare providers," said Binish Chudgar, Executive Chairman and Managing Director of Intas Pharmaceuticals. "We are pleased with the successful completion of this agreement and are excited about the future opportunities it brings for Accord BioPharma in the U.S. market."

INDICATION

UDENYCA® (pegfilgrastim-cbqv) is a leukocyte growth factor indicated to:

Accord BioPharma, Inc.
Exhibit 1056
Accord v. Janssen
IPR2026-00256, -00257, -00258, -00259

Ex. 1056-001

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

Limitations of Use

UDENYCA is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: Patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products. Reactions have included anaphylaxis.

WARNINGS AND PRECAUTIONS:

- **Fatal splenic rupture:** Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.
- **Acute respiratory distress syndrome (ARDS):** Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue UDENYCA in patients with ARDS.
- **Serious allergic reactions, including anaphylaxis:** The majority of reported events occurred upon initial exposure. Allergic reactions, including anaphylaxis, can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue UDENYCA in patients with serious allergic reactions.
- **Allergies to Acrylics (UDENYCA ONBODY® only):** The on-body injector (OBI) for UDENYCA uses acrylic adhesive. For patients who have reactions to acrylic adhesives, use of this product may result in a significant reaction.
- **Sickle cell crises:** Severe and sometimes fatal crises have occurred. Discontinue UDENYCA if sickle cell crisis occurs.
- **Glomerulonephritis:** The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events resolved after dose reduction or discontinuation. Evaluate and consider dose-reduction or interruption of UDENYCA if causality is likely.
- **Leukocytosis:** White blood cell (WBC) counts of $100 \times 10^9/L$ or greater have been observed in patients receiving pegfilgrastim products. Monitoring of complete blood count (CBC) during UDENYCA therapy is recommended.
- **Thrombocytopenia:** Thrombocytopenia has been reported in patients receiving pegfilgrastim. Monitor platelet counts.
- **Capillary Leak Syndrome:** Has been reported after G-CSF administration, including pegfilgrastim products, and is characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. If symptoms develop, closely monitor and give standard symptomatic treatment, which may include a need for intensive care.
- **Potential for Tumor Growth Stimulatory Effects on Malignant Cells:** The granulocyte colony stimulating factor (G-CSF) receptor through which pegfilgrastim products and filgrastim products act has been found on tumor cell lines. The possibility that pegfilgrastim products act as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim products are not approved, cannot be excluded.
- **Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer:** MDS and AML have been associated with the use of pegfilgrastim in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.
- **Potential Device failures (UDENYCA ONBODY only):** Missed or partial doses have been reported for products administered via on-body injectors due to the device not performing as intended. In the event of a missed or partial dose, patients may be at increased risk of events such as neutropenia, febrile neutropenia and/or infection than if the dose had been correctly delivered. Instruct patients using the OBI to notify their healthcare professional immediately to determine the need for a replacement dose of UDENYCA if they suspect that the device may not have performed as intended.
- **Aortitis:** Has been reported in patients receiving pegfilgrastim products, occurring as early as the first week after start of therapy. Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count). Consider aortitis when signs and symptoms develop without known etiology. Discontinue UDENYCA if aortitis is suspected.
- **Nuclear Imaging:** Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. Consider when interpreting bone imaging results.

ADVERSE REACTIONS: Most common adverse reactions ($\geq 5\%$ difference in incidence compared to placebo) are bone pain and pain in extremity.

To report SUSPECTED ADVERSE REACTIONS, contact 1-800-4-UDENYCA (1-800-483-3692) or notify the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

UDENYCA® Prefilled Syringe: 6 mg/0.6 mL in a single-dose prefilled syringe for manual use only.

UDENYCA® Autoinjector: 6 mg/0.6 mL in a single-dose prefilled autoinjector.

UDENYCA ONBODY®: 6 mg/0.6 mL in a single-dose prefilled syringe co-packaged with the on-body injector for UDENYCA®.

Full Prescribing Information, including Patient Information and Instructions For Use, is available at www.UDENYCA.com.

Advisors

Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P. acted as legal counsel to Accord and Intas with respect to the Transaction.

About Intas Pharmaceuticals

Intas Pharmaceuticals is a pioneer in biosimilars, having developed and launched one of the highest numbers of indigenous biosimilars in India. Intas Pharmaceuticals has a rich history of making quality biosimilars accessible to the masses in India. Intas' products like Neukine (filgrastim), Pegasta (Pegfilgrastim), Mabtas (rituximab), Razumab (ranibizumab) and Bevatas (bevacizumab) have transformed the management of their respective therapies in India. Eleftha is the latest testament to Intas' Biosimilar for Billions philosophy, fulfilling its commitment to provide quality care to the masses in India. Intas' biosimilars are manufactured at Intas Pharmaceuticals' European Union- Good Manufacturing Practices (EU-GMP) certified biotechnology plant located near Ahmedabad, Gujarat. For more information, visit www.intaspharma.com.

About Accord BioPharma

Accord BioPharma, Inc., the U.S. specialty division of Intas Pharmaceuticals, seeks to provide affordable, accessible, patient-centric therapies in oncology, immunology, and critical care. With a focus on improving the patient experience, Accord BioPharma goes beyond the biology of medicine to see disease from the patients' perspective and develop high-quality therapies that impact patients' lives. Accord BioPharma believes in the ability of biosimilars to increase access to a number of biologic medicines, that in the past may not have been considered for patients due to their high costs. Accord BioPharma looks forward to providing one of the deepest biosimilar portfolios in the industry. For more information, visit AccordBioPharma.com.

About Coherus BioSciences

Coherus BioSciences, Inc. is a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Coherus is developing an innovative immuno-oncology pipeline that is expected to be synergistic with its proven commercial capabilities in oncology.

References:

1. UDENYCA Prescribing Information. Coherus BioSciences; December 2023.

All trademarks, logos and brand names are the property of their respective owners.

Contact: abipr@accord-healthcare.com

SOURCE Accord BioPharma

21% more press release views
with **Amplify™**

Request a Demo