

PRESS RELEASE

Biocon Biologics Announces U.S. FDA Approval for Jobevne™, Biosimilar Bevacizumab, Expanding Its Oncology Portfolio

BRIDGEWATER, New Jersey and BENGALURU, Karnataka, India, April 10, 2025

Biocon Biologics Ltd (BBL), a subsidiary of Biocon Ltd (BSE code: 532523, NSE: BIOCON), today announced that the U.S. Food and Drug Administration (U.S. FDA) has approved Jobevne™ (bevacizumab-nwgd), a biosimilar Bevacizumab for intravenous use. JOBEVNE, a recombinant humanized monoclonal antibody used to treat several different types of cancer, is a biosimilar to the reference product Avastin® (bevacizumab). JOBEVNE is a vascular endothelial growth factor (VEGF) inhibitor that binds with VEGF and blocks the interaction with its receptors to prevent angiogenesis – combating cancer by restricting blood supply to the tumor.

The approval of JOBEVNE expands Biocon Biologics' biosimilar oncology portfolio in the United States, which also includes OGIVRI (Trastuzumab-dkst) and FULPHILA (Pegfilgrastim-jmdb). The Company also markets Bevacizumab in Europe (approved February 2021) and Canada (approved November 2021) under the name ABEVMY.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd., said: “The U.S. FDA approval of JOBEVNE™ (bevacizumab-nwgd) is a significant milestone—our seventh biosimilar approved in the U.S. and a strong addition to our robust oncology portfolio. It underscores the depth of our scientific expertise and commitment to expanding access to high-quality, affordable biologics. We look forward to working with all stakeholders to bring more treatment options to patients.”

In the U.S., sales of bevacizumab were approximately \$2.0 billion in 2023.**

Biocon Biologics is a leading global player in biosimilars and insulin production and has achieved many “firsts” in the industry including the first to receive approval of a trastuzumab in the United States, OGIVRI (Trastuzumab-dkst), as well as FULPHILA (Pegfilgrastim-jmdb) and the first U.S. approval of an interchangeable biosimilar for SEMGLEE (insulin glargine). Serving over 5 million patients annually, Biocon Biologics has a comprehensive portfolio of in-market and in-development biosimilar products across multiple therapies, including seven approved biosimilars in the United States and six in Canada, with a robust development pipeline of 20 biosimilar assets, including insulins and monoclonal antibodies spanning multiple therapy areas.

About JOBEVNE:

The approval for JOBEVNE (bevacizumab-nwgd) was based on a comprehensive package of comparative pharmacokinetic, safety, efficacy, nonclinical, structural, analytical and functional data, which confirmed that JOBEVNE is highly similar to Avastin® (bevacizumab).

The data demonstrated that there were no clinically meaningful differences between JOBEVNE and Avastin® in terms of pharmacokinetics, safety, efficacy, and immunogenicity.

INDICATIONS AND USAGE:

JOBEVNE is a vascular endothelial growth factor inhibitor indicated for the treatment of:

- Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first-or second-line treatment.*
- Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan-or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen.*
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment.
- Recurrent glioblastoma in adults.
- Metastatic renal cell carcinoma in combination with interferon alfa.
- Persistent, recurrent, or metastatic advanced cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan.
- Epithelial ovarian, fallopian tube, or primary peritoneal cancer:
 - in combination with carboplatin and paclitaxel, followed by JOBEVNE as a single agent, for stage III or IV disease following initial surgical resection
 - in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens
 - in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by JOBEVNE as a single agent, for platinum-sensitive recurrent disease

* Limitations of Use: JOBEVNE is not indicated for adjuvant treatment of colon cancer.

WARNINGS AND PRECAUTIONS:

- **Gastrointestinal Perforations and Fistula:** Discontinue for gastrointestinal perforations, tracheoesophageal fistula, Grade 4 fistula, or fistula formation involving any organ
- **Surgery and Wound Healing Complications:** In patients who experience wound healing complications during JOBEVNE treatment, withhold JOBEVNE until adequate wound healing. Withhold for at least 28 days prior to elective surgery. Do not administer JOBEVNE for at least 28 days following a major surgery, and until adequate wound healing. The safety of resumption of bevacizumab products after resolution of wound healing complication has not been established. Discontinue for wound healing complications of necrotizing fasciitis.
- **Hemorrhage:** Severe or fatal hemorrhages have occurred. Do not administer for recent hemoptysis. Discontinue for Grade 3-4 hemorrhage.
- **Arterial Thromboembolic Events (ATE):** Discontinue for severe ATE.
- **Venous Thromboembolic Events (VTE):** Discontinue for Grade 4 VTE.

- Hypertension: Monitor blood pressure and treat hypertension. Withhold until medically controlled; resume once controlled. Discontinue for hypertensive crisis or hypertensive encephalopathy.
- Posterior Reversible Encephalopathy Syndrome (PRES): Discontinue.
- Renal Injury and Proteinuria: Monitor urine protein. Discontinue for nephrotic syndrome. Withhold until less than 2 grams of protein in urine.
- Infusion-Related Reactions: Decrease rate for infusion-related reactions. Discontinue for severe infusion-related reactions and administer medical therapy.
- Embryo-Fetal Toxicity: May cause fetal harm. Advise females of potential risk to fetus and need for use of effective contraception.
- Ovarian Failure: Advise females of the potential risk.
- Congestive Heart Failure (CHF): Discontinue JOBEVNE in patients who develop CHF.

Please refer to full Prescribing Information for Jobevne™ (bevacizumab-nwgd) for more information. To report SUSPECTED ADVERSE REACTIONS, contact Biocon Biologics at 1-833-986-1468 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

JOBEVNE is a trademark of Biosimilars Newco Limited, a Biocon Biologics Company.

OGIVRI, FULPHILA, SEMGLEE and ABEVMY are registered trademarks of Biosimilars Newco Limited, a Biocon Biologics Company.

BIOCON BIOLOGICS and the Biocon Biologics Logo are registered trademarks of Biocon Biologics Limited.

All other trademarks are the property of their respective owners.

**Sales projections are based on Biocon Biologics' analysis of IQVIA 2023 data.

About Biocon Biologics Limited:

Biocon Biologics Ltd. (BBL), a subsidiary of Biocon Limited, is a unique, fully integrated, global biosimilars company committed to transforming healthcare and transforming lives. It is capitalizing on its 'lab to market' capabilities to serve millions of patients across 120+ countries by enabling affordable access to high quality biosimilars. The Company is leveraging cutting-edge science, innovative tech platforms, global scale manufacturing capabilities and world-class quality systems to lower costs of biological therapeutics while improving healthcare outcomes.

Biocon Biologics has commercialized nine biosimilars from its pipeline of 20 products in key emerging markets and advanced markets like U.S., Europe, Australia, Canada, and Japan. It's pipeline has several biosimilar assets under development across diabetology, oncology, immunology, ophthalmology, and other non-communicable diseases. The Company has many 'firsts' to its credit in the biosimilars industry. As part of its environmental, social and governance (ESG) commitment, it is advancing the health of patients, people, and the planet to achieve key UN Sustainable Development Goals (SDGs).

Website www.bioconbiologics.com; Follow us on X (formerly Twitter): [@BioconBiologics](https://twitter.com/BioconBiologics) and **LinkedIn:** [Biocon Biologics](https://www.linkedin.com/company/biocon-biologics) for company updates.

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as Generic Formulations in the US, Europe & key emerging markets. It also has a pipeline of promising novel assets in immunotherapy under development.

Website: www.biocon.com; Follow-us on X (formerly Twitter) [@bioconlimited](https://twitter.com/bioconlimited) and **LinkedIn:** [Biocon](https://www.linkedin.com/company/biocon) for company updates.

Forward-Looking Statements: Biocon

This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.

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