ISSUE
I
Volume
10
JAN-MAR
2026

Seven Hills Times

AN OFFICIAL PUBLICATION OF
DEPARTMENT OF PHARMACY PRACTICE,
SEVEN HILLS COLLEGE OF PHARMACY
[AUTONOMOUS]
Venkatramapuram, Ramachandrapuram (Mandal), TIRUPATI (Dist), TIRUPATI - 517 561, A.P, INDIA
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IN ASSOCIATION WITH
SRI PADMAVATHI MEDICAL COLLEGE FOR WOMEN HOSPITAL (SPMCWH)- SVIMS, Tirupati, AP, INDIA.

Clinical Applications and Challenges of Biosimilars in Modern Therapy: A Comprehensive Review

Dr. K. Harini

Abstract:

ABiosimilars are biologic medical products that are highly similar to approved reference biologics, with no clinically meaningful differences in safety, efficacy, and quality. The increasing burden of chronic diseases and the high cost of biologic therapies have driven the development of biosimilars as cost-effective alternatives. This review provides a comprehensive overview of biosimilars, including their development, regulatory pathways, clinical applications, advantages, and challenges. Biosimilars have demonstrated significant utility in oncology, autoimmune disorders, endocrinology, and gastroenterology. Despite their benefits, challenges such as manufacturing complexity, immunogenicity, regulatory hurdles, and limited acceptance among healthcare professionals persist. The role of clinical pharmacists in promoting biosimilar use and ensuring patient safety is also discussed. Overall, biosimilars hold great potential in improving healthcare accessibility and reducing treatment costs, but strategic efforts are required to overcome existing barriers.

KeyWords :Biosimilars, Biologics, Immunogenicity, Clinical Applications, Regulatory,Challenges, Monoclonal Antibodies

Introduction :

Biologic drugs have transformed modern medicine by offering targeted and effective therapies for chronic and life-threatening diseases such as cancer, autoimmune disorders, and diabetes. These drugs are derived from living cells using advanced biotechnological processes and include monoclonal antibodies, recombinant proteins, and vaccines. Despite their clinical effectiveness, biologics are associated with high costs, limiting their accessibility, especially in developing countries like India [1, 2].

Biosimilars were introduced as cost-effective alternatives to innovator biologics following the expiration of patents. Unlike generic drugs, which are identical copies of small-molecule drugs, biosimilars are highly similar but not identical due to their complex structure and sensitive manufacturing processes [1, 3]. Regulatory authorities define biosimilars as biological products that demonstrate no clinically meaningful differences from the reference biologic in terms of safety, efficacy, and quality. [2, 4]

The increasing burden of chronic diseases and rising healthcare expenditure have accelerated the demand for affordable therapeutic options. Biosimilars have emerged as a promising solution by reducing treatment costs and improving patient access to essential medicines [5,6] However, their adoption in clinical practice is still challenged by factors such as immunogenicity concerns, regulatory complexities, and limited awareness among healthcare professionals [3,4]

Vision

To emerge as one of the premier pharmacy colleges in the country and produce pharmacy professionals of global standards.

Mission

1. To deliver quality academic programs in Pharmacy and empower the students to meet Industrial Standards.

2. To build student community with high ethical standards to undertake R&D in thrust areas of national and international needs.

3. To extend outreach programs for the health care needs of the society

4. To develop industry institute interaction and foster entrepreneurial spirit among graduates.

Standard Practice

Drug Information Center Drug Formulary Management ADR Reporting Patient Counseling Drug Information Resources Prescription Audit Medication Error Reporting Antimicrobial Stewardship Journal Club Activities

This review aims to provide a comprehensive overview of biosimilars, focusing on their development, regulatory aspects, clinical applications, advantages, and challenges in modern therapy.

Biologics vs Biosimilars vs Generics

Biologics are complex macromolecules produced using living organisms and include therapeutic proteins such as monoclonal antibodies and hormones. Their structural complexity and sensitivity to manufacturing conditions distinguish them from conventional drugs [2].

Biosimilars are biologic products that are highly similar to an approved reference biologic, with no significant differences in clinical performance [1]. In contrast, generic drugs are chemically identical to their reference products and are easier to manufacture [3].

Thus, while generics are exact copies, biosimilars are highly similar but not identical due to inherent biological variability.

Development and Manufacturing of Biosimilars

The development of biosimilars involves a stepwise approach:

Analytical Studies

Extensive physicochemical and biological characterization is performed to demonstrate similarity with the reference product [1].

Preclinical Studies

Non-clinical studies assess toxicity and biological activity [3].

Clinical Studies

Clinical trials evaluate pharmacokinetics (PK), pharmacodynamics (PD), efficacy, safety, and immunogenicity [4].

Manufacturing Challenges

Manufacturing biosimilars is highly complex because they are produced in living cells. Small variations in:

·Cell lines
·Culture conditions
·Purification processes

Can significantly impact product quality [3] . Maintaining consistency across batches is a major challenge.

Regulatory Pathways

Regulatory agencies such as the FDA, EMA, and CDSCO have established strict guidelines for biosimilar approval. These include:

·Demonstration of biosimilarity through analytical studies
·Comparative clinical evaluation
·Immunogenicity assessment
·Post-marketing surveillance

Unlike innovator biologics, biosimilars follow an abbreviated approval pathway, reducing development time and cost [2, 5]

Clinical Applications of Biosimilars

Oncology

Biosimilars are widely used in cancer therapy. Trastuzumab and bevacizumab biosimilars have shown comparable efficacy and safety in breast and colorectal cancers [6].

Autoimmune Diseases

·Rheumatoid arthritis
·Psoriasis
·Ankylosing spondylitis

Drugs like adalimumab and infliximab biosimilars improve disease control at lower costs [1,4]

Gastroenterology

·Crohn's disease
·Ulcerative colitis

They are effective for long-term disease management [1].

Endocrinology

·Insulin biosimilars provide affordable options for diabetes management, especially in resource-limited settings [5].

Hematology

·Biosimilars such as erythropoietin and filgrastim are used in anemia and neutropenia [6].

Advantages of Biosimilars

1.Cost Reduction: Biosimilars are significantly cheaper than biologics, reducing healthcare expenditure [5].

2.**Improved Access**: Lower cost increases accessibility to life-saving therapies [1].

3.Market Competition: Encourages competition and reduces drug prices [6].

4.**Comparable Clinical Outcomes:** Studies confirm similar efficacy and safety profiles [4].

Challenges of Biosimilars

1.**Manufacturing Complexity:** Production in living systems makes biosimilars difficult to replicate precisely.

2.**Immunogenicity:** Potential immune responses may affect drug safety and efficacy.

3.Regulatory Barriers: Different global regulatory requirements complicate approval and marketing.

1.**Interchangeability Issues:** Not all biosimilars are automatically interchangeable with reference biologics.
2.Physician and Patient Acceptance: Lack of awareness and trust limits adoption.
3.**Market and Patent Issues**: Patent litigation and competition from originator companies delay market entry.

Future Perspectives

The future of biosimilars is promising due to:

- Increasing approvals
- Advancements in biotechnology
- Supportive regulatory policies
- Emerging trends include:
- Personalized medicine
- AI-driven drug development
- Integration with pharmacogenomics

Conclusion

Biosimilars represent a major advancement in modern therapeutics by offering cost-effective alternatives to expensive biologic drugs. Their wide range of clinical applications and economic benefits make them essential for improving healthcare accessibility. However, challenges related to manufacturing, regulation, and acceptance must be addressed. With continued research and awareness, biosimilars will play a crucial role in the future of global healthcare.

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The "Patent Cliff" of pharmacy market Drugs losing exclusivity by 2030, a critical trend starting in 2026

Aarthi.M
Pharm D IV Year

Introduction :

The pharmaceutical industry is undergoing a major change as patent exclusivity expires for popular drugs, highlighting vast generic drug opportunities. This shift will open up a $236 billion opportunity for generic and biosimilar manufacturers between 2025 and 2030. This significant loss of patent protection means more than just the end of exclusive rights. It will revolutionize the market, making affordable generics accessible to patients who require life-saving treatments, new medications, and essential therapies.

The term “patent cliff” refers to a key event in the pharmaceutical industry when many patents for branded drugs expire within a few years. When these patents expire, generic drug manufacturers can enter the market and create cheaper versions of the patented drugs.

How the generic drugs make place in the market?

Once a brand-name drug’s patent expires, generic manufacturers can produce and sell their versions without any legal issues. They usually prepare in advance, so they are ready to launch as soon as the patent protection ends, seizing immediate generic drug opportunities.

The advantages that generics gain during a patent expiry:

- **Cost structure advantages**: Generic companies have much lower costs than brand-name companies because they don’t have to spend the same amount on drug discovery and development. Instead of going through extensive trials, they can demonstrate that their drugs are equivalent to the branded versions, reducing costs significantly.

- **Competitive pricing advantages**: Generics often sell their drugs for 30-50% less than the brand-name drugs, making them attractive to patients and insurance companies. As more generics enter the market, competition drives prices even lower, and sometimes by as much as 80-90%.

- **Global market advantages:** The patent cliff especially benefits generic manufacturers in developing countries where high drug prices are unaffordable, allowing them to serve these markets profitably while offering lower prices.

- **Patient access improvements**: Patients gain increased access to affordable medicines through generic alternatives. It removes financial barriers to essential treatments as well as improves medication adherence rates across populations.

Therapeutic areas where the Generic drugs takes growth:

The best opportunities in the drug market are in complex therapeutic areas where popular drugs are losing their patent protection:

1. Oncology: This is the fastest-growing area in the generics market, with an expected annual growth rate of 9.21% until 2030. Major immuno-oncology drugs like Keytruda and Opdivo will lose patent protection in 2028, creating a huge opportunity for biosimilar developers.

2. Diabetes and Obesity: The market for GLP-1 receptor agonists is very active. Patents for drugs like Ozempic and Trulicity are running out, allowing generic and biosimilar manufacturers to enter a market with high global demand.

3. Immunology and Monoclonal Antibodies (mAbs): The global market for mAbs is expected to reach $804 billion by 2033. With patents expiring for popular drugs like Enbrel, Stelara, and Cosentyx, there is a potential $25 billion opportunity for biosimilar manufacturers by 2029.

4. Cardiovascular: There are good opportunities in the anticoagulant market as key drugs like Eliquis and Xarelto will lose patent protection.

Some of the drugs that are going to be expired under patent 2025-2030

Conclusion:

For generic and biosimilar manufacturers, the upcoming patent cliff from 2026 to 2030 offers a revolutionary $236 billion opportunity that will change access to vital treatments globally. Generics will reduce costs and improve patient adherence by taking advantage of expirations in high-value fields like cancer, diabetes, immunology, and cardiovascular treatments. While emerging markets in the Asia-Pacific, led by China and India, become hotspots for growth and investment in generic drug opportunities, innovators must adjust with strong defense strategies. In the end, this period of transition promises a fairer healthcare environment, encouraging competition and innovation for the benefit of people everywhere.

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2.DrugPatentWatch. The Patent Cliff Playbook: Pharmaceutical IP valuation, generic entry timing, and biosimilar strategy. Published March 10, 2026. Accessed April 9, 2026
3.Drug Discovery News (DDN Magazine). Blockbuster drugs face a massive patent cliff in 2026. Published February 24, 2026. Accessed April 9, 2026.

SL.NO.	Drug Name (Generic Name)	Company	Therapeutic Area	Projected Patent Expiration
1	Ozempic (semaglutide)	Novo Nordisk	Diabetes	2025 (March) – 2026
2	Eliquis (apixaban)	Bristol Myers Squibb/Pfizer	Cardiovascular	2025 (February) – 2029
3	Ibrance (palbociclib)	Pfizer	Pfizer	2025 (August) – 2027
4	Xarelto (rivaroxaban)	Johnson & Johnson/Bayer	Cardiovascular	2025 (May) – 2026
5	Dupixent (dupilumab)	Regeneron/Sanofi	Immunology	2025 (November) – 2027
6	Ocrevus (ocrelizumab)	Roche	Multiple Sclerosis	2025 (December) – 2029
7	Repatha (evolocumab)	Amgen	Cardiovascular	2028 – 2030

ICOTYDE

D. Dharani sai
Pharm D IV year

·**Generic Name**: Icotrokinra hydrochloride
·**Drug Class**: Interleukin-23 (IL-23) receptor antagonist
·**Brand Name:** Icotyde
·**Company**: Johnson & Johnson Innovative Medicine
·**Approval Date:** March 17, 2026 (FDA)
·**Dosage Form:** Oral tablets, once daily
·**Price:** Not yet disclosed (expected to be premium, J&J projects >$5 billion annual sales)
·**Indication:**Moderate-to-severe plaque psoriasis (adults & pediatric patients ≥12 years, ≥40 kg)

Description :

Icotrokinra is an IL-23 receptor antagonist, in the form of a hydrochloride salt. Icotrokinra is a 13-amino acid peptide. The molecular formula for icotrokinra is C90H120N20O22S2 and its molecular weight is 1898.17.

Icotrokinra hydrochloride is a white to almost white powder. It is freely soluble below pH 2, very slightly soluble at pH 5, practically insoluble at pH 9, and freely soluble above pH 11. The isoelectric point (pI) of the compound is 7.15. ICOTYDE™ (icotrokinra) tablets are supplied as 200 mg film-coated tablets for oral administration. Each tablet of ICOTYDE contains 200 mg icotrokinra (equivalent to 201.6-202.8 mg of icotrokinra hydrochloride)

CLINICAL PHARMACOLOGY:

Mechanism of Action Icotrokinra is a peptide that selectively binds to the IL-23 receptor (IL-23R) with a dissociation constant of 7 pM and antagonizes the binding of IL-23. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Icotrokinra inhibits the IL-23/IL-23Rdependent release of proinflammatory cytokines.

Pharmacokinetics:

Absorption:

Icotrokinra median (min, max) time to maximum plasma concentration (Tmax) is 2 (0.25, 8) hours. Effect of Food Icotrokinra AUC decreased by 43% and Cmax decreased by 59% following administration with a high-fat meal (1000 calories, 50% fat) [see Dosage and Administration (2.2)]. No clinically significant differences in icotrokinra pharmacokinetics were observed following administration of caffeine.

Distribution:

Icotrokinra is 52% bound to plasma protein. Blood to plasma partition ratio is 0.53. Icotrokinra steady state apparent (oral) volume of distribution is 92800 L. Elimination Icotrokinra median elimination half-life is 12 hours with an apparent (oral) clearance of 6550 L/h.

Metabolism:

Icotrokinra is a peptide and it is metabolized by peptide catabolism into smaller peptides. Excretion:

Following oral administration of icotrokinra to healthy subjects, approximately 37% to 81% of the dose was recovered in feces within 24 hours as unchanged icotrokinra, and 0.001% of the dose was recovered in urine as unchanged icotrokinra.

Drug Interaction Studies:

Clinical Studies

No formal drug-drug interaction studies have been conducted with icotrokinra. No clinically significant drug interactions have been identified.

CONTRAINDICATIONS:

None

ADVERSE REACTIONS:

Under the clinical trail experience of the drug ICOTYDE in comparision with the PLACEBO it is found that the possible ADRs that can occur were :

Headache, Nausea, Fatigue, Cough, Fungal infection.

WARNINGS AND PRECAUTIONS:

Infections:

Medicines that interact with the immune system may increase the risk of infection.

Avoid treatment with ICOTYDE in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing ICOTYDE. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection and/or is not responding to standard therapy, monitor the patient closely and discontinue ICOTYDE until the infection resolves.

Tuberculosis:

Consider evaluating patients for tuberculosis (TB) infection prior to initiating treatment with ICOTYDE based on clinical judgement. Consider anti-TB therapy prior to initiating ICOTYDE in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after ICOTYDE treatment. Avoid administering ICOTYDE to patients with active TB.

Immunizations:

Avoid use of live vaccines in patients during treatment with ICOTYDE. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Prior to initiating therapy with ICOTYDE, complete immunizations according to current immunization guidelines. No data are available on the response to live or inactive vaccines.

USE IN SPECIFIC POPULATIONS:

Pregnancy:

Risk Summary The available data on the use of ICOTYDE during pregnancy are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In an animal reproduction study in rabbits, oral administration of icotrokinra to pregnant rabbits during the period of organogenesis at a dose 157 times the maximum recommended human dose (MRHD) based on AUC comparison resulted in maternal body weight loss, low food consumption, late pregnancy loss, and an increased fetal incidence of fused ribs .

Lactation:

There are no data on the presence of icotrokinra in human milk, the effects on the breastfed infant, or the effects on milk production.

In a pre- and post-natal development study in rats, icotrokinra was administered orally to pregnant rats during pregnancy and lactation periods at doses up to 200 mg/kg/day (127 times the MRHD based on AUC comparison). Although not directly measured in rat milk, icotrokinra was detected in the plasma of nursing rat pups. No adverse developmental effects were observed in the nursing pups

HOW SUPPLIED/STORAGE AND HANDLING:

How Supplied:

ICOTYDE (icotrokinra) tablets: 200 mg, yellowish orange to yellowish brown, oval, film-coated tablets debossed with '200' on one side and 'JNJ' on the other side. ICOTYDE is supplied in bottles of 30 tablets, with a silica gel desiccant and a child-resistant closure.

Storage and Handling:

Store at 20 °C to 25 °C (68 °F to 77 °F); excursions permitted between 15 °C to 30 °C (59 °F to 86 °F). Store in original package to protect from moisture. Do not discard desiccant.

Reference:

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Ovarian Cancer Advances: The approval of Lifyorli (relacorilant) for platinum-resistant ovarian cancer

Y.Susmitha
Pharm D IV Year

·**Drug Name:** Lifyorli (relacorilant)
·**Generic Name:** Relacorilant
·**Drug Class:** Glucocorticoid receptor antagonist (antiglucocorticoid)
·**Company: Corcept** Therapeutics Inc.
·**FDA Approval Date:** March 25, 2026
·**Formulation:** Oral capsules (25 mg, 200 mg)
·**Legal Status:** Prescription-only

·**INDICATIONS AND USAGE:**

· LIFYORLI is indicated in combination with nab-paclitaxel for the treatment of adults with platinum resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens, at least one of which included bevacizumab .

·**Recommended Dosage and Administration :**

·The recommended dosage of LIFYORLI is 150 mg orally once on the day before, the day of, and the day after each nab-paclitaxel infusion until disease progression or unacceptable toxicity.

·The recommended dosage for nab-paclitaxel is 80 mg/m2 administered as an intravenous infusion on Days 1, 8 and 15 of each 28-day cycle until disease progression or unacceptable toxicity.

·**CLINICAL PHARMACOLOGY :**

· **Mechanism of Action:**

Relacorilant is a reversible glucocorticoid receptor (GR) antagonist. In functional in vitro assays with the mineralocorticoid receptor, relacorilant showed no agonist or antagonist activity. In human cell line derived xenograft models, relacorilant enhanced apoptosis and antitumor activity when administered with paclitaxel. Cortisol binding to the GR is immunosuppressive, decreasing secretion of pro-inflammatory cytokines. GR antagonism may indirectly activate the immune system; relacorilant inhibited the cortisol-induced reduction of tumor necrosis factor alpha and interferon gamma in stimulated peripheral blood mononuclear cells.

Pharmacokinetics:

·**Absorption:**

· Relacorilant median (min, max) time to maximum plasma concentration (Tmax) is 2.5 hours.

Effect of Food:

Relacorilant Cmax increased 1.7-fold, AUC increased 2-fold, and Tmax was delayed 0.5 hours following administration with a low-fat meal (approximately 400 to 500 calories, 25% fat content).

· Relacorilant Cmax increased 1.9-fold, AUC increased 2.4-fold, and Tmax was delayed 0.25 hours following administration with a high-fat meal (approximately 800 to 1,000 calories, 50% fat content).

·**Distribution:**

· Relacorilant apparent volume of distribution (Vz/F) is 2490 (54%) L after a single 150 mg dose under fasted conditions. Protein binding of relacorilant in human plasma is >99% in vitro.

·**Elimination:**

· Relacorilant terminal half-life is 27 (30%) hours with an apparent total clearance of 52 (69%) L/h under fasted conditions.

· **Metabolism:**

· Relacorilant is primarily metabolized by cytosolic reductases and CYP3A. An active metabolite, CORT125295, with functional activity approximately 5-fold lower than relacorilant, represents 75% of the parent AUC.

· **Excretion:**

· After a single oral dose of radiolabeled relacorilant 250 mg to healthy participants, about 73% (< 1% unchanged) of the dose was recovered in feces and 17% (< 2% unchanged) in urine.

·**DOSAGE FORMS AND STRENGTHS Capsules:**

• 25 mg: opaque dark brown, oval soft gelatin capsules with "CR25" printed in black.
• 100 mg: opaque yellow, oblong soft gelatin capsules with "CR100" printed in black.

·**ADVERSE REACTIONS :**

The following adverse reactions are discussed in more detail in other sections of the labeling:

- Neutropenia and Severe Infections
- Adrenal Insufficiency
- Exacerbation of Conditions related with Glucocorticoids.

Adverse Reactions :Occurring in ≥10% of Patients Who Received LIFYORLI in Combination with Nab-Paclitaxel in ROSELLA.

LIFYORLI + Nab-Paclitaxel:

General disorders: Fatigue, Edema ,Pyrexia
Gastrointestinal disorders: Nausea , Diarrhea , Stomatitis
Skin and subcutaneous tissue disorders: Rash, Nail disorders
.Metabolism and nutrition disorders: Decreased appetite
Respiratory disorders: Cough
Nervous system disorders: Dizziness, Dysgeusia

DRUG INTERACTIONS:

Strong CYP3A Inducers: Avoid coadministration with LIFYORLI in combination with nab-paclitaxel.

• **CYP2C8 Inducers and Moderate CYP3A Inducers:** Monitor for reduced effectiveness for LIFYORLI in combination with nab paclitaxel.

• **CYP2C8 Inhibitors:** Monitor for increased adverse reactions and modify the dosage for adverse reactions as recommended.

• CYP3A Substrates: Avoid coadministration unless otherwise recommended.

• **Certain CYP2C8 Substrates:** Avoid coadministration unless otherwise recommended.

CONTRAINDICATIONS :

LIFYORLI is contraindicated in patients receiving systemic glucocorticoids for lifesaving purposes (e.g., immunosuppression after organ transplantation) because LIFYORLI antagonizes the effect of glucocorticoids.

WARNINGS AND PRECAUTIONS:

·Neutropenia and Severe Infections:

LIFYORLI in combination with nab-paclitaxel can cause neutropenia, including febrile neutropenia and severe infections.

Description and monitoring:

Thirty-eight percent of patients initiated granulocyte colony-stimulating factor (G-CSF) during the first or second cycle of therapy.

Monitoring:

Monitor complete blood counts prior to each weekly treatment with LIFYORLI in combination with nab-paclitaxel and as clinically indicated. Based on the severity of neutropenia, delay dose, reduce dose, or permanently discontinue LIFYORLI in combination with nab-paclitaxel. Consider short-acting G-CSF administration as applicable. Consider the possibility of concurrent adrenal insufficiency, particularly in the setting of serious infection.

·Adrenal insufficiency

LIFYORLI is a reversible glucocorticoid receptor antagonist and can cause adrenal insufficiency. Adrenal insufficiency can occur at any time during treatment with LIFYORLI. The risk of adrenal insufficiency is increased in situations of stress, such as acute illness, infection, or surgery.

Description and monitoring:

Consider whether supplemental glucocorticoids are required in the perioperative period in patients who have received LIFYORLI within 30 days of surgery.

Monitoring:

Monitor patients receiving LIFYORLI for signs and symptoms of adrenal insufficiency. Withhold LIFYORLI and administer glucocorticoid therapy if adrenal insufficiency is suspected. High doses of supplemental glucocorticoids may be needed to overcome the glucocorticoid receptor antagonism produced by LIFYORLI.

After resolution of adrenal insufficiency, resume previous dose, reduce dose, or permanently discontinue LIFYORLI based on severity**.**

·Exacerbation of Conditions Treated with Glucocorticoids:

Use of LIFYORLI in patients taking systemic glucocorticoids for other conditions (e.g., autoimmune disorders) may exacerbate these conditions. LIFYORLI is a glucocorticoid receptor antagonist that may make systemic glucocorticoids less effective. Similarly, coadministration of systemic glucocorticoids may make LIFYORLI less effective. Monitor patients for reduced effectiveness of LIFYORLI and glucocorticoids in patients receiving both.

·Embryo-fetal toxicity:

Based on data from animal studies, LIFYORLI can cause fetal harm when administered to a pregnant woman. Oral administration of relacorilant to pregnant rabbits resulted in adverse developmental outcomes, including embryo-fetal mortality. Advise pregnant women of the potential risk to a fetus. Verify pregnancy status of females of reproductive potential prior to initiating LIFYORLI treatment. Advise females of reproductive potential to use effective contraception during treatment with LIFYORLI and for 1 week after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with LIFYORLI and for 1 week after the last dose

Reference:

·U.S. Food and Drug Administration. FDA approves relacorilant with nab-paclitaxel for platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer. Published March 25, 2026. Accessed April 9, 2026.

·Corcept Therapeutics. Relacorilant plus nab-paclitaxel improves overall survival in platinum-resistant ovarian cancer: Results from the ROSELLA Phase 3 trial (NCT05257408). Published 2026. Accessed April 9, 2026.

·U.S. Food and Drug Administration. Lifyorli (relacorilant) prescribing information. Drugs@FDA. Published 2026. Accessed April 9, 2026.

·Corcept Therapeutics Inc. Relacorilant: A selective glucocorticoid receptor antagonist in oncology. Company publication. Published 2026. Accessed April 9, 2026.

New Gene Therapies
The approval of Kresladi, a hematopoietic stem cell-based gene therapy for Severe Leukocyte Adhesion Deficiency-I

S.SHANU
Pharm D IV Year

The U.S. Food and Drug Administration (FDA) has granted accelerated approval for KRESLADI™ (marnetegragene autotemcel), an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of paediatric patients with severe leukocyte adhesion deficiency-I (LAD-I) due to biallelic variants in ITGB2 without an available human leukocyte antigen-matched sibling donor for allogeneic hematopoietic stem cell transplant. This indication is approved under accelerated approval based on increase in neutrophil CD18 and CD11a surface expression.

"The approval of KRESLADI represents an important milestone for the severe LAD-I community".

LAD-I is an ultra-rare genetic paediatric disease caused by mutations in the ITGB2 gene encoding for CD18, a key protein that is expressed along CD11 integrins to facilitate leukocyte adhesion to the blood vessel wall and migration to tissues to confine and clear infections and orchestrate wound repair. Patients with severe LAD-I typically show very diminished CD11a expression. Infants with severe LAD-I suffer from recurrent, life-threatening bacterial, and fungal infections that respond poorly to antimicrobials and require frequent hospitalizations.

Epidemiology:

In the U.S., the incidence of LAD-I is estimated to range from approximately one in 100,000 to one in 200,000 live births, with roughly two-thirds of affected patients classified as having the severe form of the disease.

Dosing information:

Kresladi is supplied as a cell suspension that is administered as a one-time intravenous infusion. Patients must undergo hematopoietic stem cell mobilization followed by apheresis to obtain CD34+ cells for Kresladi manufacturing. The dosing is based on the number of CD34+ cells in the infusion bag per kg of body weight. Before infusion of Kresladi, full myeloablative conditioning must be administered.

INDICATION AND USAGE:

KRESLADI is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of paediatric patients with severe leukocyte adhesion deficiency-I (LAD-I) due to biallelic variants in ITGB2 without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplant.

This indication is approved under accelerated approval based on increase in neutrophil CD18 and CD11a surface expression. Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infections

Serious infections have occurred with KRESLADI administration. Increased susceptibility to infections may occur due to administration of myeloablative conditioning prior to KRESLADI infusion.

Monitor patients for signs and symptoms of infection before and after KRESLADI infusion and treat appropriately.

Avoid administration of KRESLADI in patients with active bloodstream infections or other serious, untreated infections.

Any blood products required after KRESLADI infusion should be irradiated.

Veno-Occlusive Disease

Veno-occlusive disease has occurred with KRESLADI treatment. Increased susceptibility to veno-occlusive disease may occur due to administration of myeloablative conditioning prior to KRESLADI infusion. Monitor patients for signs and symptoms of veno-occlusive disease including assessment of liver function tests during the first month following KRESLADI infusion.

Neutrophil Engraftment Failure

Neutrophil engraftment failure may occur after treatment with KRESLADI. Neutrophil engraftment failure is defined as failure to achieve three consecutive absolute neutrophil counts (ANC) ≥ 500 cells/microliter obtained on different days by Day 43 after infusion of KRESLADI. Monitor neutrophil counts until engraftment has been achieved. If neutrophil engraftment failure occurs in a patient treated with KRESLADI, provide rescue treatment with the back-up collection of CD34+ cells.

Delayed Platelet Engraftment

Delayed platelet engraftment may occur after treatment with KRESLADI. Monitor platelet counts and bleeding until platelet engraftment and platelet recovery are achieved.

LVV-Mediated Insertional Oncogenesis

Lentiviral vector (LVV)-mediated insertional oncogenesis may occur after treatment with KRESLADI. Hematologic malignancy is a lifelong risk and patients treated with KRESLADI may develop hematologic malignancy at any time following treatment.

Monitor for hematologic malignancies clinically, and with a complete blood count (with differential) at least annually and integration site analysis as warranted for at least 15 years after treatment with KRESLADI and as clinically indicated.

Hypersensitivity Reactions

Hypersensitivity reactions including anaphylaxis may occur with the infusion of KRESLADI. The dimethyl sulfoxide (DMSO) in KRESLADI may cause hypersensitivity reactions which may occur in patients with and without prior exposure to DMSO.Monitor patients for signs and symptoms of hypersensitivity reactions during and after KRESLADI infusion. If a hypersensitivity reaction occurs, pause infusion if ongoing and manage according to clinical practice.

Anti-Retroviral Use

Anti-retroviral medications may interfere with manufacturing of KRESLADI. If a patient requires anti-retrovirals for HIV prophylaxis, mobilization and apheresis of CD34+ cells for KRESLADI manufacturing should be delayed until HIV infection is adequately ruled out. Patients should not take anti-retroviral medications for at least one month prior to mobilization, or for the expected duration required for the elimination of the anti-retroviral medications, and until all cycles of apheresis are completed.

Interference with Serology Testing

Patients who have received KRESLADI are likely to test positive by polymerase chain reaction (PCR) assays for HIV due to LVV provirus insertion resulting in a false-positive test for HIV. Therefore, patients who have received KRESLADI should not be screened for HIV infection using a PCR-based assay.

Blood, Organ, Tissue, and Cell Donation

Patients treated with KRESLADI should not donate blood, organs, tissues, or cells for transplantation at any time in the future.

ADVERSE REACTIONS

The most common non-laboratory adverse reactions (≥ 30% of patients) include: mucositis, upper respiratory tract infection, viral infection, febrile neutropenia, skin lesion, nausea/vomiting, rash/dermatitis, pyrexia, device related infection, and skin infection.

The most common laboratory adverse reactions (≥ 30% of patients) include: hemoglobin decreased, platelet count decreased, neutrophil count decreased, leukocyte count decreased, aspartate aminotransferase increased, and alanine aminotransferase increased.

DRUG INTERACTIONS:

No formal drug interaction studies have been performed. KRESLADI is not expected to interact with the hepatic cytochrome P-450 family of enzymes or drug transporters.

Vaccines :

The safety and effectiveness of immunization with live viral vaccines during or following KRESLADI treatment has not been studied. Vaccination is not recommended during the 6 weeks preceding the start of myeloablative conditioning, and until hematological recovery following treatment with KRESLADI. Where feasible, administer childhood vaccinations prior to myeloablative conditioning for KRESLADI.

Anti-retroviral Use:

Patients should not take anti-retroviral medications for at least one month prior to initiating medications for stem cell mobilization and for the expected duration for elimination of the medications, and until all cycles of apheresis are completed . Anti-retroviral medications may interfere with manufacturing of KRESLAD

HOW SUPPLIED/STORAGE AND HANDLING:

KRESLADI is supplied in one or two infusion bags containing a frozen suspension of genetically modified autologous cells enriched for CD34+ cells in a cryo-preservative medium containing 5% DMSO and dextran 40. Each infusion bag contains approximately 30 mL and is individually packed within an overwrap in a metal cassette for protection. KRESLADI is shipped from the manufacturing facility to the infusion center in a cryoshipper, which may contain one or two cassettes intended for treatment of a single patient.

- 50 mL infusion bag and metal cassette
- Match the identity of the patient with the patient identifiers on the cassette(s) and Lot Information Sheet upon receipt.
- Keep the infusion bag in the cassette and store KRESLADI frozen in the vapor phase of liquid nitrogen at less than or equal to -150°C (≤ -238°F) until ready for thaw and administration.
- Thaw KRESLADI prior to infusion [see Dosage and Administration.
- Do not re-freeze after thawing.
- Do not irradiate KRESLADI, as this could lead to inactivation

REFERENCES:

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2. Mirasol F. FDA approval of Kresladi expands gene therapy in pediatric rare diseases. BioPharm International. Published March 31, 2026. Accessed April 9, 2026.
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NATIONAL SCIENCE DAY CELEBRATIONS -2025

A field visit to the Indian Institute of Science Education and Research (IISER) was organized on the occasion of **National Science Day** on **1st March 2026.** The visit aimed to expose students to advanced scientific research facilities, promote scientific temper, and create awareness about the importance of science in innovation and societal development. Faculty members and students enthusiastically participated in the visit and gained valuable academic exposure.

A Two-Day National Conference

A **Two-Day National Confe**rence On INTEGRATING AI, 3D PRINTING AND QUALITY ASSURANCE FOR REGULATORY READINESS conducted on **13/03/2026 and 14/03/2026** The conference explores the role of Artificial Intelligence (AI) in improving decision-making, predictive analysis, and process optimization, alongside 3D printing (additive manufacturing) for rapid prototyping and customized production. It also emphasizes the importance of quality assurance (QA) systems to ensure consistency, safety, and compliance.

Campus Placement Drive

The Department of Pharmacy Practice, in association with the Career Guidance and Campus Placement Cell, organized a Campus Drive in collaboration with Apollo Pharmacies on **9th March 2026.** The event aimed to provide students with valuable career opportunities and insights into the professional landscape of the pharmacy sector. Students actively participated in the recruitment process, which included aptitude assessments, technical interviews, and HR interactions. The interactive nature of the session allowed students to clarify their doubts regarding job roles, work culture, and career pathways in the pharmacy retail sector.

Medical Camp

A **medical camp** was successfully conducted on **6th March 2026** at O.B.R Kandriga, Vadamalapeta, Tirupati by SHCP in collaboration with global educational and welfare Society,Tirupati, with the active participation of 20 Pharm D 4th year students accompanied by SHCP Assistant Professor Dr.M.Ramya with strong Support and encouragement from the Principal,SHCP,Dr.M.Niranjan Babu .

World's Tuberculosis DAY

The Department of Pharmacy Practice organized a **World Tuberculosis Day Awareness Program** on **24th March 2026** to educate students about the significance of early diagnosis, prevention, and effective management of tuberculosis. The event was conducted with the theme "Yes! We Can End TB: Commit, Invest, Deliver."

World Women's Day Celebration

Seven Hills College of Pharmacy (Autonomous), through its NSS Unit, successfully organized **International Women's Day** on **08-03-2026**. under the theme "Rights. Justice. Action. For All Women and Girls." The program, initiated by NSS Programme Officer Prof. K. Saravanakumar, created a platform to empower women faculty members by highlighting their rights and promoting gender equality.

WORLD OBESITY DAY

World Obesity Day, observed annually on **March** 4, aims to increase awareness about obesity as a major global health concern and to promote actions for its prevention and management. For pharmacy students, this day serves as an important opportunity to understand the clinical, pharmacological, and public health aspects of obesity and the role pharmacists play in addressing this growing health issue.

GESTATIONAL DIABETIS MELLITUS Awareness Day

Gestational Diabetes Mellitus Awareness Day, observed on March 10, aims to increase awareness about Gestational Diabetes Mellitus as a significant health concern affecting pregnant women worldwide. This day highlights the importance of early screening, proper management, and preventive strategies to ensure the health and well-being of both mother and child.

Epilepsy Awareness Day

Epilepsy Awareness Week, observed annually on **March 26th** to increase understanding of epilepsy and reduce the stigma associated with the condition, highlights the importance of education, early diagnosis, and effective management of epilepsy. It serves as a platform to spread awareness about one of the most common neurological disorders affecting millions of people worldwide.

A Two-Day National Workshop

GSeven Hills College of Pharmacy (Autonomous) organized a **Two Day National Workshop** on "AI integrated Pedagogy for Industry Readiness: Earn Your ICH-GCP E6 (R3) Global Certification and Parenteral Development" in association with Rx Doctors, Chennai on **27th & 28th February, 2026** at Prof. K. Chinna Swamy Auditorium, SHCP, Tirupati. The workshop aims to enhance industry readiness among students and faculty and to provide knowledge of ICH-GCP E6 (R3) guidelines for global clinical research standards, parenteral product development and regulatory aspects and to bridge the gap between academia and pharmaceutical industry practices.

PharmaZest – Inter College Techno Cultural & Sports Fiesta

An inter-college techno-cultural sports fest is a large-scale event organized by an institution on 26/02/2026 and 27/02/2026 Time @ 9.00 am that brings together students from different colleges to participate in a wide range of technical, cultural, and sports activities. It serves as a vibrant platform where young minds showcase their talents, exchange ideas, and engage in healthy competition.

The technical segment includes events such as coding competitions, paper presentations, quizzes, robotics, and project exhibitions. These activities aim to enhance students' analytical thinking, creativity, and practical knowledge beyond the classroom. Participants get an opportunity to apply theoretical concepts to real-world challenges and interact with peers who share similar academic interests.

The cultural segment adds colour and energy to the fest through performances like dance, music, drama, fashion shows, and fine arts. It celebrates diversity and creativity, allowing students to express themselves artistically and appreciate different cultures and traditions. These events also help in building confidence and stage presence.

The main objectives are To promote technical skills through events like coding, robotics, paper presentations, and project expos

To encourage innovation, creativity, and problem-solving abilities among students

To provide a platform for knowledge sharing and learning beyond the classroom.

COMMITTEE FOR CONTROL AND SUPERVISION OF EXPERIMENTS ON ANIMALS (CCSEA)

Dr D Sujatha, Associate Professor, Institute of Pharmaceutical Technology, Sri Padmavathi Mahila Visvavidyalayam (Women's University), Tirupati-517502, AP, India. TOPIC: Refinement - Importance and Applications in Animal Experiments Dr. R. V. Suresh Kumar, Nominee of CCSEA &Professor, Dept. of Veterinary Surgery and Radiology, Sri Venkateswara Veterinary University, Tirupati-517502, A.P, India. TOPIC: Ethics and Animal Welfare in Biomedica Research Dr. B. Premkumar, Professor &HOD, Department of pharmacology, KK college of pharmacy (affiliated to the TN, Dr. MGR medical University), KRA Campus, 1/161, Sankaralinganar Road, Gerugambakkam Main Rd, Chennai, Tamil Nadu 600122. Topic: Toxicological and Pharmacological Research: In Silico, Invitro, and Invivo approches Dr. D. Sandeep, Associate Professor, Department of Pharmacology, Chebrolu Hanumaiah Institute of Pharmaceutical Sciences (CHIPS), Chandramoulipuram, Chowdavaram, Guntur -522019. Topic: Beyond 3R's -Redefining Frontiers in Pharmacological Animal Research

Address: Venkatramapuram (Via) Tanapalli,
TIRUPATI - 517561
Andhra Pradesh (India) Phone: 7702484511,
7702484513 ,9440729490 Fax: 08577-281560

Email: shcp7@yahoo.com
VISITOR COUNTER
Web Counter
CONNECT WITH US
feedback@shcpfeedback@gmail.com