



Kingdom of Saudi Arabia
Saudi Food & Drug Authority

SAUDI DRUG UPDATES (SDU)

Mar 2026

About

Saudi Drug Updates

Saudi Drug Updates is a monthly release issued by the Saudi Food and Drug Authority (SFDA) to keep healthcare professionals informed about the latest developments in pharmaceuticals. It features updates on regulatory decisions, safety communications, drug registration changes, and other topics under the Authority's oversight. The goal is to support informed decision-making and promote safe and effective medical practices.

Product Registration Updates

SFDA Drug Approvals

Application Type Drug Type	Trade Name (Scientific Name)	Strength Dosage Form	SFDA Approved Use
Registration Biological Drug	Rystiggo (Rozanolixizumab)	140 mg/ml Solution for injection	Rozanolixizumab is indicated as an add-on to standard therapy for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.
Registration Biological Drug	Voxzogo (Vosoritide)	0.4 mg, 0.56 mg, 1.2 mg, Powder and solvent for solution for injection	Vosoritide is intended for the treatment of achondroplasia in patients 4 months of age and older whose epiphyses are not closed.
Registration New Drug	Orphacol (Cholic acid)	250 mg, 50 mg Capsule, hard	Cholic acid is indicated for the treatment of inborn errors in primary bile acid synthesis due to 3 β -Hydroxy- Δ^5 -C27-steroid oxidoreductase deficiency or Δ^4 -3-Oxosteroid-5 β -reductase deficiency in infants, children and adolescents aged 1 month to 18 years and adults.
Registration NEW Drug	NEXPOVIO (Selinexor)	20 mg Film-coated tablet	Selinexor is indicated: <ul style="list-style-type: none"> • In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. • In combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.
Registration New Drug	CYSTAGON (Cysteamine)	50 mg/ 150 mg Hard Capsule	Cysteamine is indicated for the treatment of proven nephropathic cystinosis. Cysteamine reduces cystine accumulation in some cells (e.g. leukocytes, muscle and liver cells) of nephropathic cystinosis patients and, when treatment is started early, it delays the development of renal failure.

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Approved Clinical Trials on Drugs

Study Title	Investigational Medicinal Product	Sponsor / CRO	Study Sites
Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Plozasiran in Adults with Severe Hypertriglyceridemia at High Risk of Acute Pancreatitis (SHASTA-5 Study)	Plozasiran	Arrowhead Pharmaceuticals/ IQVIA	<ol style="list-style-type: none"> 1. King Faisal Specialist Hospital and Research Center (Riyadh). 2. King Saud University Medical City (Riyadh). 3. King Abdullah International Medical Research Center (Riyadh).
A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oral Inhalation of Seralutinib for the Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease (PH-ILD) Followed by a Long-Term Extension Evaluating Safety and Efficacy	Seralutinib	Gossamer Bio/ Balsam	<ol style="list-style-type: none"> 1. King Faisal Specialist Hospital and Research Center (Riyadh).
A Phase 3, Randomized, Open-label Study of Nivolumab + Relatlimab Fixed-dose Combination with Chemotherapy Versus Pembrolizumab with Chemotherapy as First-line Treatment for Participants with Non-squamous (NSQ), Stage IV or Recurrent Non-small Cell Lung Cancer and with Tumor Cell PD-L1 Expression $\geq 1\%$	Nivolumab \ Relatlimab	Bristol-Myers Squibb Services / Balsam	<ol style="list-style-type: none"> 1- King Faisal Specialist Hospital and Research Center (Jeddah). 2- King Abdulaziz Hospital NG (Riyadh) 3- King Fahad Specialist Hospital (Dammam)
Implementing pharmacogenetics in the busulfan dosing method for children undergoing hematopoietic stem-cell transplantation: a prospective, international, multicenter, randomized clinical trial.	Busulfan	King Abdullah International Medical Research Center	King Abdullah International Medical Research Center (Riyadh).
REal-World Application of Luspatercept in Adults with Transfusion-Dependent Beta-Thalassemia in the Middle East (RELATE): A non-interventional retrospective and prospective observational study	Luspatercept	PI initiated	Qatif Central Hospital (Qatif)

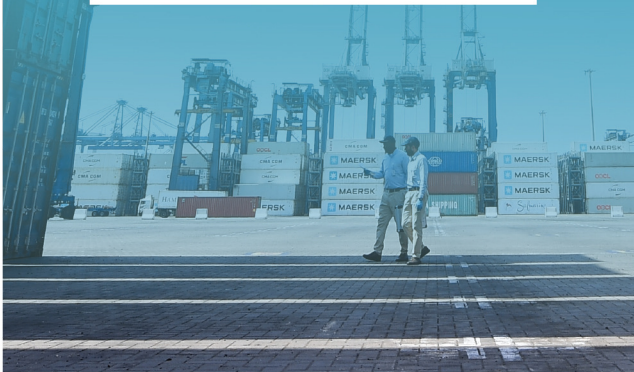
Recalls, Market Withdrawals & Safety Alerts

SFDA has issued a recall of the following Products:

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[Drug Sector Guidelines](#)

[Clinical Considerations for Vaccines](#)



SFDA Approved Risk Management Measures (RMMs)

The summary view in the table includes reviewed and approved Risk minimization measures by SFDA:

Xalkori® (Crizotinib)

Arabic Patient Card	
English Patient Card	
Arabic Patient Brochure	
English Patient Brochure	

Aubagio® (Teriflunomide)

Prescriber Guide	
English Patient Card	
Arabic Patient Card	

Zynlonta® (Loncastumab Tesirine)

Senegy® (Amlodipine/Valsartan)

DHPC	
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English Patient Card

Arabic Patient Card	
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SDU Bulletin

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Any other inquiries:

Contact Drug Sector at e-mail: drug-dept@sfda.gov.sa

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