Drug & Poison Information Center Bulletin
Faculty of Pharmacy - Tanta University

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Expanded access in pancreatic cancer: FDA perspective

Pancreatic cancer remains one of the most lethal malignancies, with limited therapeutic options and very poor survival rates. The urgent need for innovative treatments has led regulatory agencies to adopt flexible pathways to improve patient access to promising investigational drugs.

Expanded Access Program

The U.S. Food and Drug Administration (FDA) Expanded Access program allows patients with serious or life-threatening conditions to receive investigational therapies outside of clinical trials when no comparable alternatives are available. This approach aims to balance urgent clinical need with patient safety and ongoing scientific evaluation.

FDA Authorization of Daraxonrasib

Recently, the FDA permitted expanded access to **daraxonrasib**, an investigational agent targeting RAS-driven signaling pathways in pancreatic cancer. Given the high prevalence of RAS mutations in pancreatic ductal adenocarcinoma, this therapeutic strategy is considered highly relevant.

Open-Label Expanded Access Program :

The study is designed as an open-label treatment program without a placebo or comparison group, primarily aiming to provide early access to the therapy while monitoring patient safety. The study does not specify a fixed enrollment number, as it is an Expanded Access Program rather than a conventional randomized clinical trial, and it is expected to continue until approximately 2028.

EGCS ISO 9001: 2015 REGISTERED Cert. no.: 1005 / DIC 09 A

Clinical Significance

This authorization highlights the critical unmet need in pancreatic cancer management and provides selected patients with early access to a promising therapeutic option under strict medical supervision. Importantly, expanded access does not replace randomized clinical trials but complements them by addressing urgent patient needs while generating additional clinical insights.

Summary

The FDA's decision to allow expanded access to daraxonrasib reflects both the severity of pancreatic cancer and the potential of targeted therapies. Continued clinical trials are essential to establish definitive safety and efficacy before regulatory approval.

References:

- *U.S. Food and Drug Administration. FDA permits expanded access to investigational pancreatic cancer drug. Available at: https://www.fda.gov/news-events/press-announcements/fda-permits-expanded-access-investigational-pancreatic-cancer-drug. Accessed in May, 2026.*
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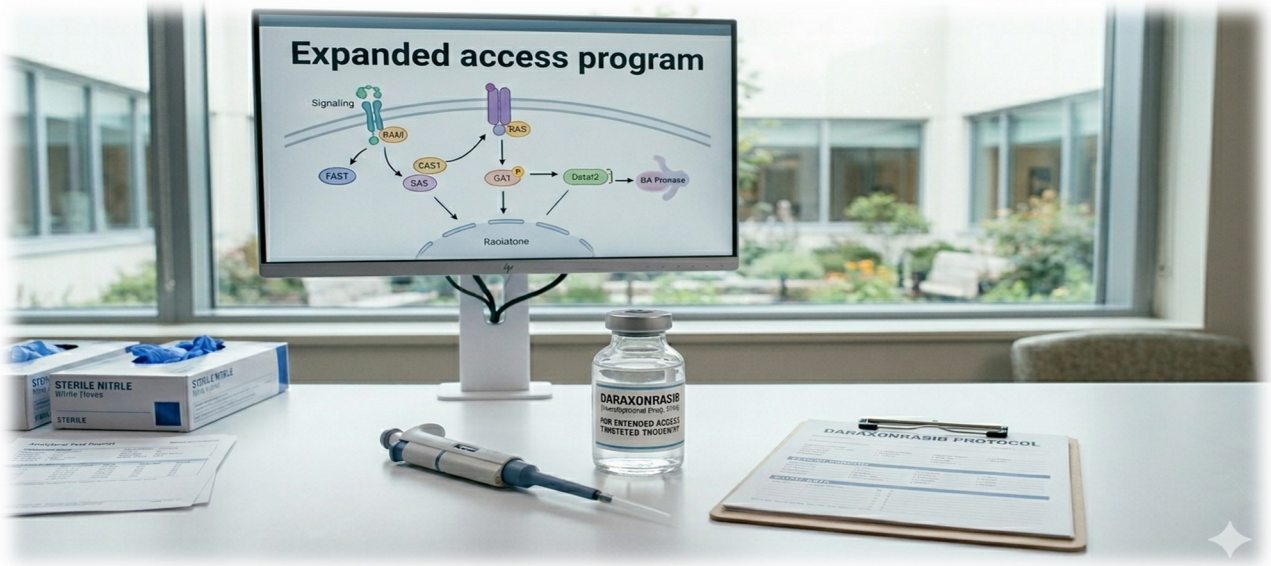
- *FDA Permits Expanded Daraxonrasib Access in Previously Treated Metastatic PDAC. Available at: https://www.cancernetwork.com/view/fda-permits-expanded-daraxonrasib-access-in-previously-treated-metastatic-pdac. Accessed in May, 2026.*
- *Expanded Access Program for Daraxonrasib (RMC-6236) in Previously Treated Metastatic Pancreatic Adenocarcinoma. Available at: https://clinicaltrials.gov/study/NCT07573215. Accessed in May, 2026.*



By: Marwa Elsayed , PGCPD, M.Sc.

GLP-1 agonists in Egypt: Benefits and clinical concerns

Egypt faces high rates of obesity and type 2 diabetes, with nearly 40% of adults affected by obesity. GLP-1 receptor agonists such as Semaglutide & Tirzepatide are effective FDA-approved treatments for diabetes and weight management. However, their growing availability in Egypt has increased off-label use and self-administration driven by social media. Prescribers should ensure appropriate patient selection, monitor adverse effects, and emphasize medical supervision with lifestyle modification.

Myth	Facts
These medications work for everyone who wants to lose weight.	They are approved for patients with clinically significant obesity (BMI ≥30) or overweight (BMI ≥27) with metabolic comorbidities.
You can stop the medication once you reach your target weight.	These medications are not a course of treatment; they are long-term disease management tools. To avoid weight regain.
There is no need to follow a diet or exercise while on these medications.	All clinical trials of these drugs were conducted alongside counselling on caloric restriction and increased physical activity.
Mounjaro and Wegovy cause diabetes in non-diabetic users.	Both medications have been shown to reduce the risk of progression to T2DM in high-risk pre-diabetic populations.
These medications cause cancer.	Both medications carry a black box warning for thyroid C-cell tumors based on rodent studies, but rats showed higher thyroid GLP-1 receptor expression than humans as human data are limited
Any doctor can prescribe these medications safely.	Safe prescribing requires understanding proper dosing, dose-titration protocols, monitoring, and management of interactions and side effects.

References:

- *GLP-1 Overdoses on the Rise: Cause for Concern?. Available at: https://www.medscape.com/viewarticle/glp-1-overdoses-rise-cause-concern-2026a1000dob?ecd=a2a. Accessed in May, 2026.*
- *Hossam A. Ghazi . Semaglutide and Tirzepatide in Egypt: A Critical Evaluation of Prescribing Trends, Off-Label Challenges, and the Influence of Social Media on Patient Perception . ESDL, 6 (1), 2026.*

By: Nagwan S. Farhoud, M.Sc.

SUN PHARMA INITIATES U.S. NATIONWIDE RECALL OF DOXORUBICIN

Sun Pharmaceutical Industries, Inc. (Sun Pharma) is voluntarily recalling specific lots of Doxorubicin Hydrochloride for Injection, USP, 2 mg/mL (20 mg/10 mL) throughout the United States.

WHY THE RECALL?

The recall is due to the potential presence of foreign particulate matter in the product, which could pose a risk to patient safety.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

PRODUCT AFFECTED

- Doxorubicin Hydrochloride for Injection, USP
- 2 mg/mL (20 mg/10 mL)
- Specific lots (see full list on FDA website)
- 10 mL Multiple Dose Vial
- NDC: 25021-152-10

SCOPE

The recall is nationwide and applies to distribution across the United States.

WHO SHOULD TAKE ACTION?

Healthcare providers, hospitals, clinics, pharmacies, and distributors should immediately:

- ✓ Check inventory
- ✓ Quarantine affected product
- ✓ Stop use and distribution

WHAT TO DO

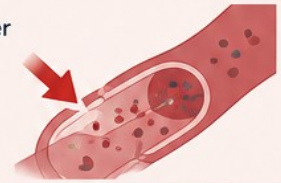
If you have any of the recalled product:

- STOP using it immediately
- Quarantine the product
- Contact your Sun Pharma representative for return instructions

POTENTIAL RISK

Injection of products containing foreign particulate matter may lead to serious adverse events, including:

- Tissue damage
- Inflammation
- Blocked blood vessels
- Other serious complications



FOR MORE INFORMATION

For the complete list of affected lot numbers and detailed information, please visit the FDA website:

www.fda.gov/recalls

SUN PHARMA

Sun Pharma is committed to patient safety and quality. We apologize for any inconvenience this may cause.

PATIENT SAFETY IS OUR PRIORITY

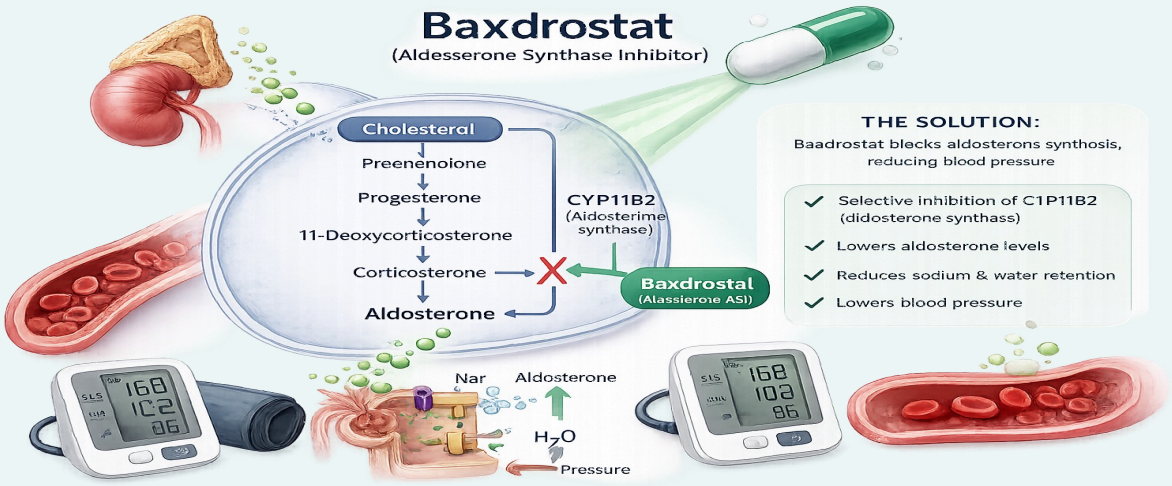
Thank you for your cooperation.

A new era in hypertension medications

⇒ Hypertension is a medical condition characterized by consistently high blood pressure levels, affecting an estimated 1.4 billion people worldwide. Over time, this can damage blood vessels and vital organs, increasing the risk of serious health problems such as heart attack, stroke, heart failure and kidney disease.

⇒ **Baxdrostat** (sold under the brand name Baxfendy) is a **first-in-class** aldosterone synthase inhibitor (ASI) developed by AstraZeneca to treat hard-to-control and resistant hypertension in adults. It works by precisely blocking the production of aldosterone, a hormone that raises blood pressure.

⇒ In the **Phase 2 BrigHTN** trial, baxdrostat reduced blood pressure in patients with resistant hypertension, with the 2 mg dose showing the most consistent effect. However, the **HALO trial** showed similar reductions in the placebo group, likely due to better medication adherence. Overall, baxdrostat demonstrated good safety with mostly mild side effects and no major impact on kidney function, and further studies are ongoing in CKD and primary hyperaldosteronism.



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- *Novel drug approvals for 2026.Available at : https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2026. Accessed in May, 2026.*
- *Baxdrostat new drug application accepted under FDA priority review in the US for patients with hard-to-control hypertension. Available at: https://www.astrazeneca.com.. Accessed in May 2026.*
- *Młynarska E, Czarnik W, Dzieża N, et al. Baxdrostat: A Next-Generation Aldosterone Synthase Inhibitor Offering New Hope in Resistant Hypertension. Biomolecules. 2025;15(10):1439.. doi:10.3390/biom15101439*

By: Nagwan S. Farhoud, M.Sc. & Marwa Elsayed, M.Sc

26 JUNE

WORLD INTERNATIONAL SUBSTANCE ABUSE DAY

Break the cycle.
Build a better future.

A global day to raise awareness about substance abuse and the importance of prevention, treatment, and recovery.

WHY IT MATTERS

- Millions of lives are affected by substance use worldwide.
- Addiction is a health issue, not a moral failing.
- Support, compassion, and access to care can help people recover.
- Prevention and early intervention build healthier, safer communities.

PREVENTION STARTS WITH ALL OF US

- Educate and empower our children and youth.
- Talk openly about substance use.
- Strengthen communities and support systems.
- Promote mental health and well-being.

HELP IS AVAILABLE

- Reach out. You are not alone.
- Seek help from trusted professionals.
- Support recovery and reduce stigma.
- Recovery is possible. Hope is real.

TOGETHER, LET'S BUILD A WORLD FREE FROM SUBSTANCE ABUSE.

AWARENESS. PREVENTION. SUPPORT. RECOVERY.

#SupportTodayForABetterTomorrow

ISO 9001:2015 initial audit visit for the Drug and Poison Information Center, Faculty of Pharmacy-Tanta University

The Drug and Poison Information Center at the Faculty of Pharmacy, Tanta University, hosted the initial review visit for **ISO 9001:2015** certification on May 12, 2026. The event included an audit of documents, records, and on-site operations by representatives from the certification body and **EGAC** to evaluate compliance with quality management standards. The audit concluded with positive feedback, confirming the center's fulfillment of ISO 9001:2015 requirements and recognizing the excellence of the center's team.

Contact us

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We are on the web

https://pha.tanta.edu.eg/units/Drug%20Information/Default.aspx

Vision

The vision of Tanta University DPIC is to improve national healthcare service through provision of evidence-based, unbiased, patient oriented drug information services & adverse drug reporting system.

Mission

* Responding to drug inquiries related to the use of the drug and providing the health care professionals and patients with drug information related to the patient's care to achieve the optimal use of the drug in addition to the provision of other toxicological managing information.
* Educational activities to support the rational optimal use of drugs as well, supporting research activities.
* Continuous medical education and training courses in various fields of pharmacy for students, undergraduates, postgraduate students, and researchers.
* Issuing a Drug Information Bulletin periodically to take a look at medical & pharmaceutical news.
* Supporting the National Pharmaceutical Vigilance Program by following up and monitoring side effects and problems related to use of pharmaceutical preparations within regional hospitals.
* Contributing to the establishment of various treatment protocols and prescription booklet services in regional hospitals.

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