



SWAMY VIVEKANANDHA COLLEGE OF PHARMACY

(Affiliated to the The Tamil Nadu Dr.MGR. Medical University, Chennai,
Approved by PCI, Accredited by NBA, New Delhi)
Elayampalayam, Tiruchengode-637 205, Namakkal (Dt), Tamil Nadu.



Department of Pharmacy Practice

Presents

ADR PULSE RADAR

(SPOT IT, STOP IT)

VMCH ADR ALERT: AUGUST 2026

'Pharmacovigilance - Passive Surveillance'

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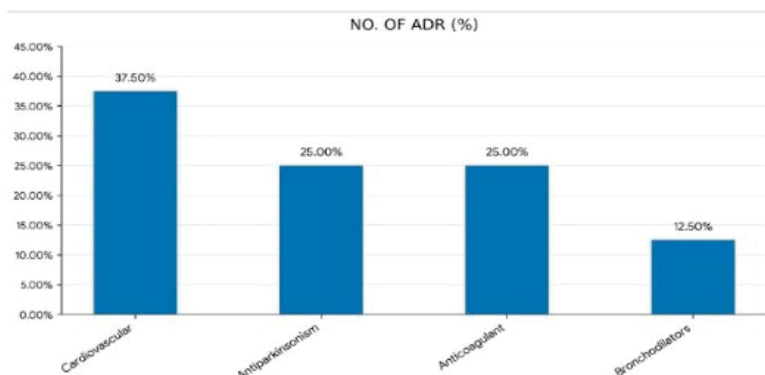


VMCH ADR SUMMARY

TOTAL ADR : 8
MOST COMMON : CARDIOVASCULAR
DRUGS- 37.50%
SERIOUS CASES : NIL

ADRs INVOLVED

Cardiovascular-37.50%, Antiparkinsonism-25%,
Anticoagulant-25%, Bronchodilators- 12.50%



IF ANY ADR, SCAN AND REPORT HERE



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FDA ANNOUNCEMENT

Genglycos (pariglasene breca-parvovec-opnr) received accelerated FDA approval for patients ≥ 8 years with glycogen storage disease type Ia (GSDIa). It is a one-time AAV8 gene therapy that delivers a functional G6PC gene to liver cells. Clinical data showed a 31% reduction in daily cornstarch requirements at 48 weeks, potentially reducing dietary burden and improving glucose control. Serious adverse effects included anaphylaxis, adrenal insufficiency, elevated lactate, and hypoglycemia. It is not recommended during pregnancy and carries warnings for liver toxicity and tumorigenicity. Further studies are needed to confirm long-term benefits.

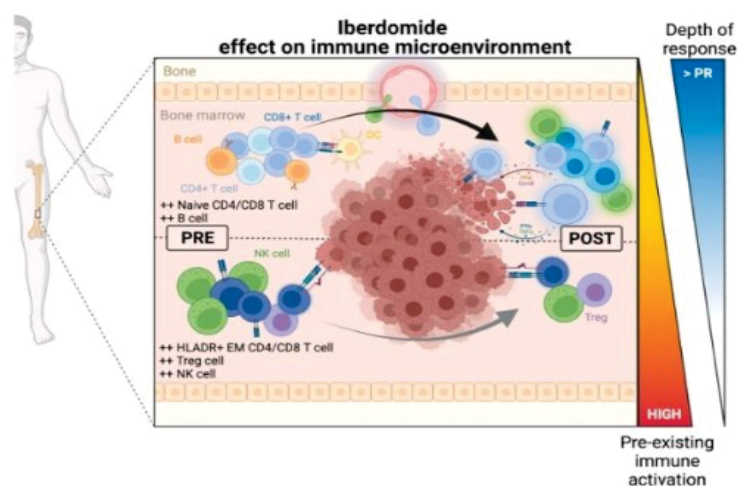
REFERENCES

- <https://outlooktherapeutics.com/pipeline/new-anti-veg-for-ophthalmic-indications>.
- <https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2026>.

FDA DRUG INFORMATION

Zenbexus (Iberdomide)

The U.S. FDA approved Zenbexus (Iberdomide) on August 13, 2026, in combination with daratumumab and hyaluronidase-fihj and dexamethasone for adults with multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent. Iberdomide is an oral cereblon E3 ligase modulator (CELMoD), that enhances the degradation of specific proteins involved in the survival of myeloma cells, thereby promoting anti-myeloma activity. Recommended dose is 1 mg once daily on Days 1–21 of a 28-day cycle.



The efficacy of the combination was evaluated in the EXCALIBER-RRMM trial. Among the primary efficacy population, the minimal residual disease-negative complete response rate was 41% with iberdomide + daratumumab/hyaluronidase-fihj + dexamethasone, compared with 21% with the comparator regimen, demonstrating a significant improvement in deep response. Major adverse effects include embryo-fetal toxicity, thromboembolism, neutropenia, infections, and secondary malignancies; it is available through the ZENBEXUS REMS program.

REFERENCES

1. Center for Drug Evaluation and Research. FDA grants accelerated approval to iberdomide with daratumumab and hyaluronidase-fihj and dexamethasone for multiple myeloma. U.S. Food and Drug Administration. FDA; 2026 [cited 2026 Aug 21]. Available from: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-iberdomide-daratumumab-and-hyaluronidase-fihj-and-dexamethasone>
2. Lonial S, Dimopoulos MA, Berdeja JG, Richardson PG, Quach H, Rodríguez-Otero P, Maciag P, Hong K, Amatangelo M, Chen M, van de Donk NW. EXCALIBER-RRMM: a phase III trial of iberdomide, daratumumab, and dexamethasone in relapsed/refractory multiple myeloma. *Future Oncology*. 2025 Jun 9;21(14):1761-9.

INVASIVE BREAST CARCINOMA

SHORT COMMUNICATION



Breast carcinoma is a malignant tumor arising from breast tissue, most commonly from the milk ducts or lobules. Invasive carcinoma occurs when cancer cells spread beyond the primary tissue into surrounding tissues, lymph nodes, or distant organs.

It may present as a breast lump with possible axillary lymph node involvement. Mammography, ultrasound, and biopsy are important for diagnosis, staging, and guiding appropriate treatment.

SUMMARY

This case highlights the critical role of early diagnostic evaluation, prompt surgical intervention (Modified Radical Mastectomy), and tailored perioperative pharmacological management in optimizing outcomes and controlling metastatic progression in patients presenting with invasive breast carcinoma.

CASE REPORT

A 52-year-old female (Mrs. A) presented with a left breast lump present for 2 months, which had rapidly increased in size, accompanied by cyclic back pain. Baseline vitals were stable (BP 130/70 mmHg, Pulse 86 bpm, 97%).

CT-Thorax revealed a left breast mass with axillary lymphadenopathy. Tru-cut biopsy confirmed Invasive Breast Carcinoma (Grade 2), and mammography demonstrated left axillary lymph node metastasis.

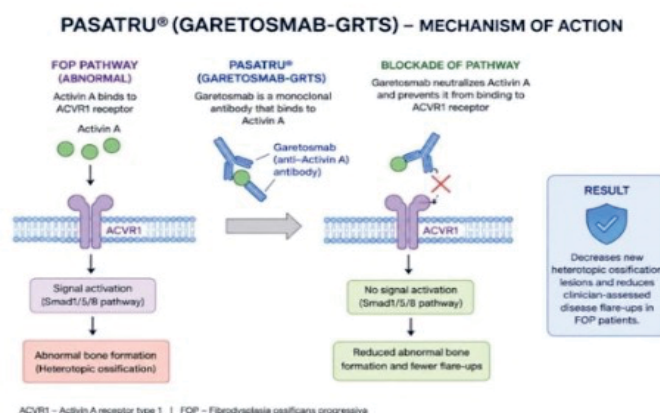
The patient successfully underwent a Left Modified Radical Mastectomy (MRM). Pre-operative care included antibiotic prophylaxis (Inj. Ceftriaxone 1g IV), gastroprotection (Inj. Pantoprazole 40mg IV), and antiemetic therapy (Inj. Ondansetron 4mg IV). Post-operative management comprised IV antibiotics (Inj. Clavam 1.2g BD), multimodal analgesia (Inj. Paracetamol, Inj. Tramadol, Tab. Chymoral Forte), fluid resuscitation, and clinical monitoring for recovery.

**-R L . GAYATHRI,M.S. GOPIKAA SHRI
V- PHARM. D**

FDA DRUG INFORMATION

Pasatru (garetoismab-grts)

The U.S. FDA approved Pasatru (garetoismab-grts) on August 19, 2026, for adults with fibrodysplasia ossificans progressiva (FOP) to reduce the formation of new heterotopic ossification lesions and clinician-assessed disease flare-ups. FOP is a rare genetic disorder caused by abnormal signaling through the activin A receptor type 1 pathway, resulting in progressive formation of bone in soft tissues such as muscles, tendons, and ligaments. Garetoismab is a fully human monoclonal antibody that blocks Activin A, thereby reducing abnormal bone formation. The recommended starting dose is 10 mg/kg administered as an intravenous infusion over 60 minutes once every four weeks. If the 10 mg/kg dose is not tolerated, the dose may be reduced to 3 mg/kg once every four weeks. The efficacy of Pasatru was evaluated in a randomized, double-blind, placebo-controlled clinical trial involving 63 adults with FOP. Patients received garetoismab 3 mg/kg, garetoismab 10 mg/kg, or placebo by intravenous infusion every four weeks for 56 weeks. At Week 56, both garetoismab doses significantly reduced the formation of new heterotopic ossification lesions compared with placebo. The 10 mg/kg group had 2 new lesions among 23 patients, while the 3 mg/kg group had 1 new lesion among 19 patients, compared with 19 new lesions among 21 patients receiving placebo.



Clinician-assessed disease flare-ups were also reduced, with 9 flare-ups in the 10 mg/kg group, 53 in the 3 mg/kg group, and 66 with placebo. Major safety concerns include fetal harm, skin and soft tissue infections, and epistaxis requiring medical intervention. The most common adverse reactions include epistaxis, hypertrichosis, abscesses, and acne. Pasatru received Breakthrough Therapy, Fast Track, Orphan Drug, and Priority Review designations from the FDA.

REFERENCES

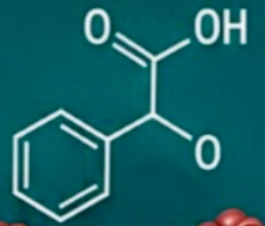
- 1.Center for Drug Evaluation and Research. FDA approves second treatment for fibrodysplasia ossificans progressiva. U.S. Food and Drug Administration. FDA; 2026 [cited 2026 Aug 22]. [FDA official approval announcement](#)
- 2.Regeneron Pharmaceuticals, Inc. Pasatru (garetoismab-grts) approved by U.S. FDA for adults with fibrodysplasia ossificans progressiva. Regeneron Pharmaceuticals; 2026



ADR CASE

NICOUMALONE INDUCED MALENA

IN PATIENT DIAGNOSED WITH CAD



PATIENT DETAILS



Age : 68 Year



Sex : Male



Drug : Nicoumalone



Dose : 2 mg



Route of Administration : P/O, Tablet



Starting Date : 27/07/2026



Stop Date : 07/08/2026

(Nicoumalone was stopped due to malena)



Reaction Date : 07/08/2026



CAUSALITY ASSESSMENT

WHO UMC
(PROBABLE)



OUTCOME

RECOVERED



MANAGEMENT

THE DRUG WAS STOPPED AND PATIENT WAS TREATED SUPPORTIVELY. MALENA RESOLVED AND PATIENT RECOVERED.



Gastrointestinal bleeding
(Malena)



Nicoumalone
(2 mg Tablet)



Black tarry stool
(Malena)



Anticoagulant



Used in CAD



Can cause bleeding
(Malena)





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"Vidhya Rathna"

Prof. Dr. M. KARUNANITHI, B.Pharm., M.S., Ph.D., D.Litt.,
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