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

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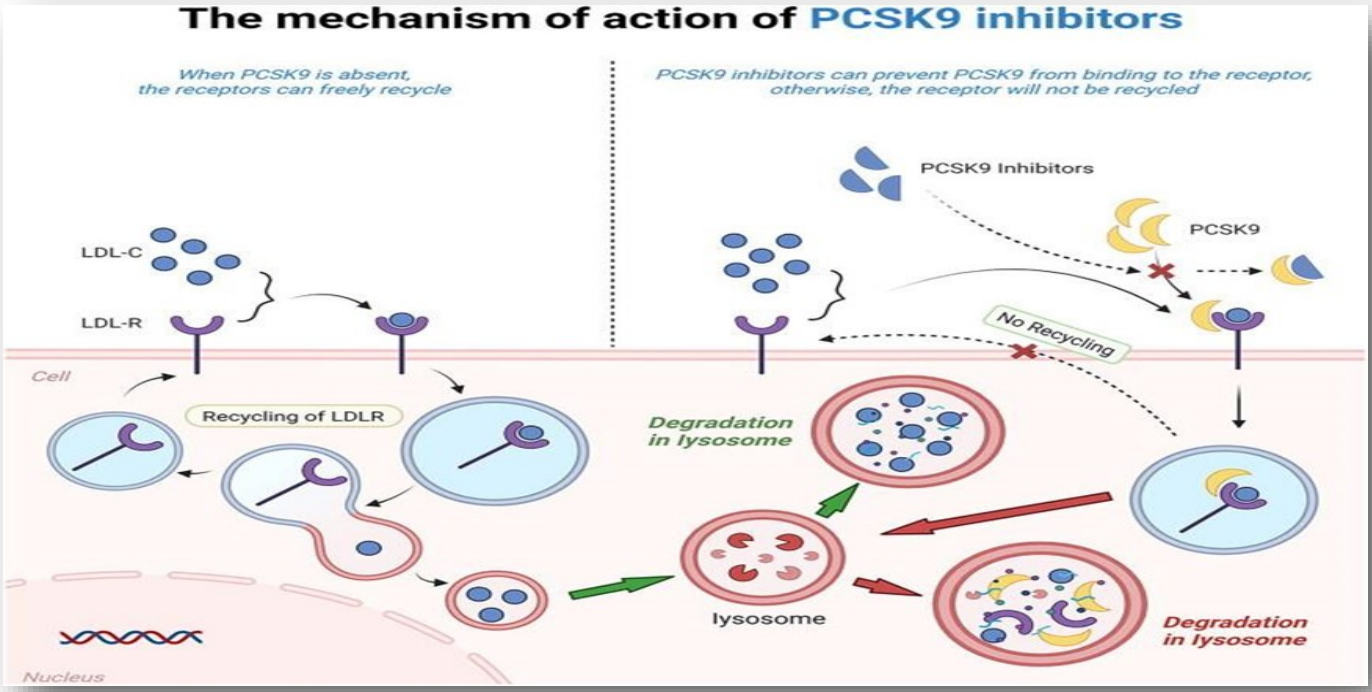
A New Era in Cholesterol Management: First Oral PCSK9 Inhibitor Receives FDA Approval

The U.S. Food and Drug Administration (FDA) approved Lipfendra (enlicitide), developed by Merck Sharp & Dohme LLC, as the first oral inhibitor of proprotein convertase subtilisin/kexin type 9 (PCSK9). It is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH).

Pharmacological Target and Mechanism of Action

Enlicitide is a small-molecule inhibitor of PCSK9, a key regulator of hepatic low-density lipoprotein receptor (LDLR) metabolism, that promotes lysosomal degradation of LDL receptors, reducing hepatic uptake of circulating LDL-C. Inhibition of PCSK9 preserves LDL receptors on the hepatocyte surface, thereby enhancing LDL-C clearance from the circulation and reducing plasma LDL-C concentrations. Enlicitide, therefore provides a novel oral approach to PCSK9 inhibition, in contrast to previously available injectable PCSK9-targeting therapies.



FDA-Approved Indication and Therapeutic Position

The FDA approved Lipfendra (enlicitide) as an adjunct to diet and exercise for reducing LDL-C in adults with hypercholesterolemia, including patients with HeFH. The once-daily oral formulation provides an additional therapeutic option for patients who require further LDL-C reduction despite existing lipid-lowering therapy. Its approval expands the therapeutic options targeting the PCSK9 pathway beyond currently available injectable agents.

Clinical Efficacy, Safety, and Therapeutic Implications

Enlicitide demonstrated substantial LDL-C lowering in two randomized, double-blind, placebo-controlled trials involving 3,207 adults receiving maximally tolerated statin therapy. At Week 24, LDL-C was reduced by 56% in patients with established ASCVD or high cardiovascular risk and by 59% in patients with HeFH, compared with placebo. The safety profile was generally comparable with placebo, although diarrhea and dizziness were reported more frequently in the HeFH trial. As the first once-daily oral PCSK9 inhibitor, enlicitide provides a convenient new option for patients requiring additional LDL-C reduction, while its long-term cardiovascular outcomes and ultimate place in therapy remain to be further established.

References:

- Navar AM, Mikhailova E, Catapano AL, et al. A Placebo-Controlled Trial of the Oral PCSK9 Inhibitor Enlicitide. *N Engl J Med*. 2026;394(6):529-539. doi:10.1056/NEJMoa2511002
- FDA Approves First Oral PCSK9 Inhibitor to Lower LDL Cholesterol in Adults with High Cholesterol | FDA Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-pcsk9-inhibitor-lower-ldl-cholesterol-adults-high-cholesterol?. Accessed in August, 2026.

By: Mai Mousa , PharmD, M.Sc. , PhD., Candidate

Upcoming Pharmacy Conferences in 2026

The First-in-Class CNS Stimulant for ADHD in Adults and Children

On July 24, 2026, the FDA granted approval of centanafadine (Simtriyo, Otsuka) as a first-in-class treatment of attention-deficit/hyperactivity disorder (ADHD) in adults and pediatric patients 6 years of age and older weighing at least 20 kg.

ADHD is a developmental condition of inattention and distractibility, with or without accompanying hyperactivity.

Centanafadine is a norepinephrine-dopamine-serotonin reuptake inhibitor and a central nervous system stimulant. The mechanism of action of centanafadine in the treatment of ADHD is unclear; however, its efficacy could be mediated through its activity as a norepinephrine-dopamine-serotonin reuptake inhibitor.

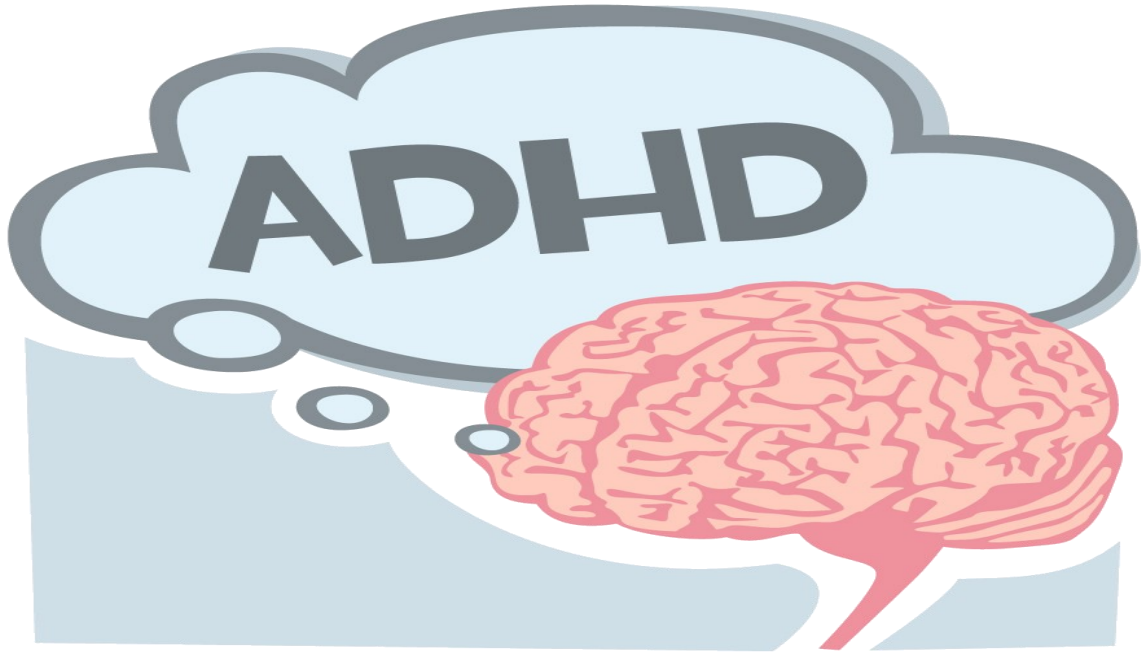
The approval is supported by results from four phase 3 clinical trials evaluating the efficacy and safety of centanafadine across adult, adolescent, and pediatric patients.

In combined results from two phase 3 trials, with total participants of more than 800 adults, more patients who received centanafadine had at least an 18-point improvement at week 6 on the (ADHD Investigator Symptom Rating Scale) total scores compared with patients who received placebo. Additionally, improvements were observed as early as week 1.

Results from two phase 3 trials with children between the ages of 6 and 12 years and adolescents between 13 and 17 years showed significant improvements in ADHD Rating Scale-5 total scores in children and adolescents who received a high dose of the medication vs. those receiving placebo.

The most common side effects reported during these trials were decreased appetite, nausea, rash, headache, and abdominal pain in children and adolescents, as well as headache, decreased appetite, insomnia, nausea, dry mouth, and diarrhea in adults.

Simtriyo has a Boxed Warning, the FDA's most prominent safety warning, for the risk of suicidal thoughts and behaviors in children and for the risk of abuse, misuse, and addiction.



References:

- Simtriyo FDA Label. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/218145s000lbl.pdf. Accessed in July, 2026
- FDA Approves First NDSRI for ADHD in Adults and Children. Available at: https://www.medscape.com/viewarticle/fda-approves-first-ndsri-adhd-adults-and-children-2026a1000pfg. Accessed in July, 2026.
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By: Amr Noweir, B.Sc

Smarter Heart Checks: What You Need to Know about AI Stethoscopes

AI-enabled digital stethoscopes enhance physical exams by integrating digital audio recording and ECG sensors. These devices use deep-learning software for real-time analysis of heart sounds and rhythms, improving early detection of heart conditions. The article discusses their functionality, diagnostic performance, and clinical utility.

Key Takeaways & Evidence: AI stethoscopes capture two key data streams simultaneously:

- **Phonocardiograms (PCG):** Detailed recordings of heart sounds to detect murmurs.
- **Single-Lead ECG:** Heart rhythm strips to detect electrical abnormalities.

Conditions Identified: The software rapidly flags early signs of:

- **Atrial Fibrillation (AF):** Irregular heart rhythms.
- **Heart Failure (HF):** Reduced pumping efficiency / low ejection fraction.
- **Valvular Heart Disease (VHD):** Structural valve defects, showing **more than double the sensitivity** for moderate-to-severe VHD compared to standard clinical exams.

Point-of-Care Speed: Analyzes sound and electrical patterns within **15 seconds** during a routine primary care visit.

Clinical Considerations: AI Stethoscopes:

Screening adjuncts help identify early risk factors, requiring secondary confirmation via ECG or echocardiogram. Proactive interventions address asymptomatic abnormalities, aiming to minimize long-term cardiac damage and prevent hospitalizations. Key challenges to adoption include EHR integration, provider training, and reimbursement models.

References:

- AI Stethoscopes May Aid Early CVD Detection. Available at: https://www.medscape.com/viewarticle/ai-stethoscopes-may-aid-early-cvd-detection-2026a1000smt?src=. Accessed in August, 2026.
- AI stethoscope revolutionises heart failure diagnosis. Available at: https://digital.nhs.uk/data-and-information/keeping-data-safe-and-benefitting-the-public/powerful-moments/ai-stethoscope-revolutionises-heart-failure-diagnosis. Accessed in August, 2026.

By: Marwa Elsayed, PGCPD., M.Sc.

From our Received Inquiries in 2026

Initial Question

Is there any problem to take antihypertensive drugs and Foradil (formoterol) inhalation ?

Background Information

A 77 years old male patient on bisoprolol drug for management hypertension and recently he had bronchitis and physician prescribed formoterol.

Ultimate Question

Drug-drug interaction between formoterol and bisoprolol.

Response

Bisoprolol decreases effects of formoterol by pharmacodynamics-antagonism. So use with caution and monitor for the effect of formoterol.

References:

- Can you take Bisoprolol with Formoterol?. Available at: https://www.drugs.com/drug-interactions/bisoprolol-with-formoterol-393-0-1136-0.html. Accessed in August, 2026.
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We are on the web

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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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