Patients in the US undergo first doses of GE HealthCare's new PET radiotracer, Flyrcado (flurpiridaz F 18) injection

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- The first patient doses of GE HealthCare's new FDA-approved PET radiotracer, Flyrcado ™(flurpiridaz F 18) injection, are being administered at early adopter sites around the United States.
- First-of-its-kind radiopharmaceutical, Flyrcado, a PET myocardial perfusion imaging (MPI) agent, delivers higher diagnostic efficacy in patients with known or suspected coronary artery disease (CAD), compared to SPECT MPI, the predominant procedure used in nuclear cardiology today.
- Available as a ready-to-use unit dose, Flyrcado can expand clinician and patient access to PET MPI and is expected to be available to nearly all of the existing cardiac PET centers in the US by the end of 2025.
- GE HealthCare has filed its pass-through application for Flyrcado with the US Centers for Medicaid and Medicare (CMS) to secure procedural codes and reimbursement rates which will further enhance access to the tracer.

ARLINGTON HEIGHTS, Ill.--(BUSINESS WIRE)--Feb. 25, 2025-- GE HealthCare (Nasdaq: GEHC) has delivered the first patient doses of Flyrcado™ (flurpiridaz F 18) injection, a first-of-its-kind unit dose positron emission tomography myocardial perfusion imaging (PET MPI) agent for the detection of coronary artery disease (CAD), at early adopter imaging centers in the US. This milestone follows the recent FDA approval of Flyrcado, which is indicated for patients with known or suspected CAD, and delivers higher diagnostic efficacy compared to single-photon emission computed tomography (SPECT) MPI, the predominant procedure used in nuclear cardiology today.

Dr. Mouaz Al-Mallah, MD, MSc, MASNC, Director of Cardiac PET at Houston Methodist Hospital, said, "Flyrcado opens new frontiers for cardiac PET with a significantly longer half-life than existing PET MPI tracers, and we are proud to be one of the first to use it in our cardiac PET lab. The longer half-life eliminates the need for onsite tracer manufacturing so it can be ordered as a ready-to-use unit dose. Additionally, it offers clinicians the flexibility to perform exercise stress testing—something not feasible with any previously available cardiac PET tracer. We anticipate Flyrcado will make PET MPI more accessible to clinicians and patients and allow more centers to provide this important imaging modality to appropriate patients."

This month, Houston Methodist Hospital delivered the first doses in a phased rollout of the cardiac PET agent at early adopter imaging centers nationwide, which includes UW Health University Hospital in Wisconsin. Full commercialization of the radiotracer is anticipated in the second quarter of 2025. With a half-life of 109 minutes—significantly longer than existing PET MPI tracers—Flyrcado removes the need for on-site tracer productior and generator maintenance and enables distribution to a wide network of hospitals and imaging centers. GE HealthCare will be supported by contract manufacturing organizations (CMOs) to expand coverage across the US to enable regional access to Flyrcado and expects to be able to reach nearly all of the existing cardiac PET user base by the end of 2025.

"The first patient doses of Flyrcado mark a significant milestone in the journey of this product which has been more than a decade in the making," said Kevin O'Neill, CEO of the Pharmaceutical Diagnostics (PDx) segment of GE HealthCare. "These imaging centers are leading the way in cardiac imaging, and we are pleased they have recognized the impact this diagnostic—which has been called a game-changer—can make both for their clinicians and their patients. We are committed to growing the manufacturing footprint for Flyrcado to drive access for cardiac PET-enabled imaging centers throughout the US."

CAD is the most common form of heart disease and remains the leading cause of death for men and women in the US, with 371,506 deaths reported in 2022[1]. During the multicenter international AURORA Phase III trial, flurpiridaz F 18 was compared with both invasive coronary angiography as a standard of truth to determine diagnostic efficacy in detecting CAD, as well as with SPECT MPI. Around six million MPI procedures are undertaken each year in the US[2] to show blood flow through the heart muscle and evaluate the presence, extent and degree of myocardial ischemia or infarction. Flyrcado brings the first practical opportunity to combine exercise stress testing with cardiac PET imaging for CAD, enabling the most robust protocol for evaluating ischemia in patients.

GE HealthCare will mark the commercial launch of Flyrcado at the annual American College of Cardiology congress in Chicago from March 29-31, 2025, and expects to receive pass-through status from the US Centers for Medicaid and Medicare (CMS) shortly thereafter, enabling separate reimbursement for Flyrcado in the hospital outpatient setting. This would facilitate patient access and enhance diagnostic capabilities for clinicians. GE HealthCare is also collaborating with commercial payers to ensure Flyrcado is recognized for its value and potential to improve patient outcomes and thus becomes a covered benefit for in-network beneficiaries.

As a leading global medical technology and pharmaceutical diagnostics innovator, GE HealthCare provides both molecular imaging equipment and radiopharmaceuticals used across cardiology, neurology and oncology. The PDx segment is a global leader in imaging agents which supported over 130 million patient procedures in 2024, equivalent to four patient procedures every second.

Forward-Looking Statements

This release contains forward-looking statements. These forward-looking statements might be identified by words, and variations of words, such as "will," "expect," "may," "would," "could," "plan," "believe," "anticipate," "intend," "potential," and similar expressions. These forward-looking statements may include, but are not limited to, statements about Flyrcado and GE HealthCare Technologies Inc.'s (the "Company's") performance, growth opportunities, and strategy. These forward-looking statements involve risks and uncertainties, many of which are beyond the control of the Company. Factors that could cause the Company's actual results to differ materially from those described in its forward-looking statements include, but are not

limited to, uncertainties regarding the commercial success of Flyrcado, the Company's ability to receive pass-through status from the US Centers for Medicaid and Medicare, and decisions by regulatory authorities impacting labeling, manufacturing processes, safety, or other matters that could affect the availability or commercial potential of Flyrcado. Other factors that may cause such a difference also include those discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission and any updates or amendments it makes in future filings. There may be other factors not presently known to the Company or which it currently considers to be immaterial that could cause the Company's actual results to differ materially from those projected in any forward-looking statements the Company makes. The Company does not undertake any obligation to update or revise its forward-looking statements except as required by applicable law or regulation.

1. National Center for Health Statistics. Multiple Cause of Death 2018–2022 on CDC WONDER Database. Accessed May 3, 2024. https://wonder.cdc.gov/mcd.html
2. Miller, R. J. H., Bednarski, B. P., Pieszko, K., Kwiecinski, J., Williams, M. C., Shanbhag, A., Liang, J. X., Huang, C., Sharir, T., Hauser, M. T., Dorbala, S., Di Carli, M. F., Fish, M. B., Ruddy, T. D., Bateman, T. M., Einstein, A. J., Kaufmann, P. A., Miller, E. J., Sinusas, A. J., Acampa, W., Han, D., Dey, D., Berman, D. S., & Slomka, P. J. (2024). Clinical phenotypes among patients with normal cardiac perfusion using unsupervised learning: A retrospective observational study. *EBioMedicine*, 99, 104930. https://doi.org/10.1016/j.ebiom.2023.104930

About GE HealthCare Technologies Inc.

GE HealthCare is a trusted partner and leading global healthcare solutions provider, innovating medical technology, pharmaceutical diagnostics, and integrated, cloud-first AI-enabled solutions, services and data analytics. We aim to make hospitals and health systems more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 125 years, GE HealthCare is advancing personalized, connected and compassionate care, while simplifying the patient's journey across care pathways. Together, our Imaging, Advanced Visualization Solutions, Patient Care Solutions and Pharmaceutical Diagnostics businesses help improve patient care from screening and diagnosis to therapy and monitoring. We are a $19.7 billion business with approximately 53,000 colleagues working to create a world where healthcare has no limits.

GE HealthCare is proud to be among 2025 Fortune World's Most Admired Companies™.

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https://www.gehealthcare.com/products/molecular-imaging-agents/flyrcado

Important Safety Information and Usage of Flyrcado™ (flurpiridaz F 18) injection

FLYRCADO™ (flurpiridaz F 18) injection, for intravenous use important safety information

Indications and Usage

FLYRCADO is a radioactive diagnostic drug indicated for positron emission tomography (PET) myocardial perfusion imaging (MPI) under rest or stress (pharmacologic or exercise) in adult patients with known or suspected coronary artery disease (CAD) to evaluate for myocardial ischemia and infarction.

Contraindications

None

Warnings and Precautions

- Risk associated with exercise or pharmacologic stress: Patients evaluated with exercise or pharmacologic stress may experience serious adverse reactions such as myocardial infarction, arrhythmia, hypotension, bronchoconstriction, stroke, and seizure. Perform stress testing in the setting where cardiac resuscitation equipment and trained staff are readily available. When pharmacologic stress is selected as an alternative to exercise, perform the procedure in accordance with the pharmacologic stress agent's prescribing information.
- Radiation risks: FLYRCADO contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe handling to minimize radiation exposure to patients and health care providers. Advise patients to hydrate before and after administration and to void.

Adverse Reactions

- Most common adverse reactions occurring during FLYRCADO PET MPI under rest and stress (pharmacologic or exercise) (incidence ≥ 2%) are dyspnea, headache, angina pectoris, chest pain, fatigue, ST segment changes, flushing, nausea, abdominal pain, dizziness, and arrhythmia.

Use in Specific Populations

- Pregnancy
    - There are no data on use of flurpiridaz F 18 in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. If considering FLYRCADO administration to a pregnant woman, inform the patient about the potential for adverse pregnancy outcomes based on the radiation

dose from flurpiridaz F 18 and the gestational timing of exposure.
    - FLYRCADO contains ethanol (a maximum daily dose of 337 mg anhydrous ethanol). If considering FLYRCADO administration to a pregnant woman, inform the patient about the potential for adverse pregnancy outcomes associated with ethanol exposure during pregnancy.
- Lactation
    - Temporarily discontinue breastfeeding. A lactating woman should pump and discard breastmilk for at least 8 hours after FLYRCADO administration.
- Pediatric Use
    - Safety and effectiveness of FLYRCADO in pediatric patients have not been established.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800-654-0118 (option 2 then option 1) or by email at GPV.drugsafety@gehealthcare.com or FDA at 800-FDA-1088 or www.fda.gov/medwatch

For full prescribing information, click here. For important safety information, please click here.

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