ACC 2025: GE HealthCare announces the U.S. launch of pivotal innovations that will help transform the cardiology care pathway

March 27, 2025

- The much-anticipated Flyrcado™ (flurpiridaz F 18) injection, a first-of-its-kind unit dose positron emission tomography myocardial perfusion imaging agent for the detection of coronary artery disease, is now available in select U.S. markets and has been granted traditional pass-through payment status by the U.S. Centers for Medicare and Medicaid.

CHICAGO--(BUSINESS WIRE)--Mar. 27, 2025-- GE HealthCare (Nasdaq: GEHC) today announced the U.S. launch of Flyrcado™ (flurpiridaz F 18) injection at the 2025 American College of Cardiology (ACC) Annual Scientific Session & Expo, taking place March 29-31 in Chicago. Additionally, the company will showcase new AI-powered innovations, reflecting its strategy to leverage AI to help increase efficiency and enable seamless integration of data across the cardiology care pathway. GE HealthCare has been investing in AI for years and has topped the FDA list of AI-enabled device authorizations for three years in a row with 85 authorizations.[i]

“The future of healthcare lies in the integration of advanced technologies with human expertise, allowing for a more holistic, data-driven and efficient cardiology care pathway,” said Eigil Samset, general manager of Cardiology Solutions at GE HealthCare. “Cardiovascular diseases are the leading cause of death globally, so it is critical that we continue our commitment to innovations in this space – our newest solutions showcased at ACC will help transform and optimize the diagnostic workflow.”

Flyrcado U.S. launch and U.S. Centers for Medicare and Medicaid (CMS) pass-through status

In 2024, the FDA approved Flyrcado for patients with known or suspected coronary artery disease (CAD), delivering higher diagnostic efficacy compared to single-photon emission computed tomography (SPECT)[ii] myocardial perfusion imaging (MPI), the predominant procedure used in nuclear cardiology today.

Around six million MPI procedures are undertaken each year in the U.S.[iii] to show blood flow through the heart muscle and evaluate the presence, extent and degree of myocardial ischemia or infarction. PET is the most effective form of MPI for detecting CAD[iv] and is recommended for a wide range of patients, including those considered more challenging to diagnose, such as individuals with a BMI greater than 30 or women, especially those with dense breasts[v], over SPECT MPI. With its 109-minute half-life, Flyrcado can be ordered as a ready-to-use unit dose and offers clinicians the first practical opportunity to combine exercise stress testing with cardiac PET imaging for CAD, providing a highly effective protocol for evaluating ischemia in patients.

Today, GE HealthCare announced the commercial launch of Flyrcado, a first-of-its-kind unit dose positron emission tomography myocardial perfusion imaging (PET MPI) agent, now available in select U.S. markets. This launch coincides with the receipt of pass-through status by the CMS, effective April 1st, securing a drug-specific Healthcare Common Procedure Coding System (HCPCS) billing code and coverage for traditional Medicare beneficiaries. Pass-through payment status—typically granted to facilitate patient access to innovative devices and drugs—will enable CMS to provide separate payments for the radiopharmaceutical and the PET-CT scan, when performed with Flyrcado in the hospital outpatient setting.

“The launch of Flyrcado represents a significant advancement in cardiac care, providing a new, highly effective diagnostic tool for those with known or suspected coronary artery disease,” said Eric Ruedinger, vice president and general manager of GE HealthCare’s Pharmaceutical Diagnostics segment for the U.S. and Canada. “With the grant of pass-through status by CMS, and the official commercial launch of Flyrcado, we are pleased that millions of patients throughout the U.S. will have access to this innovative technology, which will help improve diagnostic accuracy and may lead to better patient outcomes."

Flyrcado will be unveiled at ACC on Saturday, March 29, and throughout the conference, clinicians from several clinical trial and early adopter sites will participate in learning lab sessions, innovation stage talks, and 'Meet the Expert' breakout sessions to share their experiences and insights on using Flyrcado. You can learn more about these events and how to participate here.

Additional innovations highlighted at ACC 2025:

- The latest version of **CASE™ (Cardiac Assessment System for Stress Testing),** powered by our CardioSoft™ technology, will be unveiled at ACC on Sunday, March 30. CASE is designed to enable clinicians to unlock insights quickly while ensuring seamless data flow, which could be critical for cardiac patients. The scalable portfolio provides on-demand access to high-quality ECG data and integrates into existing workflows. The advanced tools of CASE are aimed to support diverse cardiovascular disease patients, empower confident diagnosis and assist clinicians to promptly place patients on the appropriate care pathway.
- **CardIQ Suite** is an integrated workflow for the seamless review of calcium scoring and cardiac computed tomography angiography (CCTA) data. The suite features a fully automated calcium scoring algorithm that quickly identifies calcium burden and location, providing both total and per territory scores within seconds, and includes the ability to visualize and estimate the volume of heart fat.[vi] Additionally, readers can immediately proceed to the CCTA read using advanced 2D and automated 3D processing tools as well as enjoy automated coronary segmentation and tracking AI algorithms to significantly reduce the need for manual intervention, enhancing efficiency with ready-to-read multi-planar images.

- The recently introduced **AltiX AI.i edition of Mac-Lab™, CardioLab™ and ComboLab** editions aim to improve the user experience, elevate workflow in the cardiac catheterization lab and support even the most complex electrophysiology procedures. The AltiX AI.i edition of Mac-Lab, CardioLab and ComboLab is designed to enhance efficiency and precision care for multiple types of cardiac procedures. These latest editions offer new features that streamline workflow and enhance interoperability, while upholding strong cybersecurity standards. AltiX AI.i is available for order in the U.S. and is expected to launch in global markets later this year.[vii]

To learn more about the cardiology innovations GE HealthCare will be featuring at ACC 2025, please visit the events page here or stop by booth #9013.

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.

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.

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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[i] "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," December 20, 2024, https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

[ii] Maddahi, J, Agostini, D, Bateman, T. et al. Flurpiridaz F-18 PET Myocardial Perfusion Imaging in Patients With Suspected Coronary Artery Disease. *JACC*. 2023 Oct, 82 (16) 1598–1610. https://doi.org/10.1016/j.jacc.2023.08.016

[iii] 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

[iv] 1. Driessen RS, Raijmakers PG, Stuijfzand WJ, Knaapen P. Myocardial perfusion imaging with PET. Int J Cardiovasc Imaging. 2017;33(7):1021-1031.

[v] Bateman TM, Dilsizian V, Beanlands RS, DePuey EG, Heller GV, Wolinsky DA. American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET. J Nucl Med . 2016;57(10):1654-1656.

[vi] CardIQ Suite is 510(k) pending at the U.S. FDA. It is not CE marked. Not available for sale in the U.S. or EU countries.

[vii] AltiX AI.i is 510(k) cleared and CE mark pending.

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