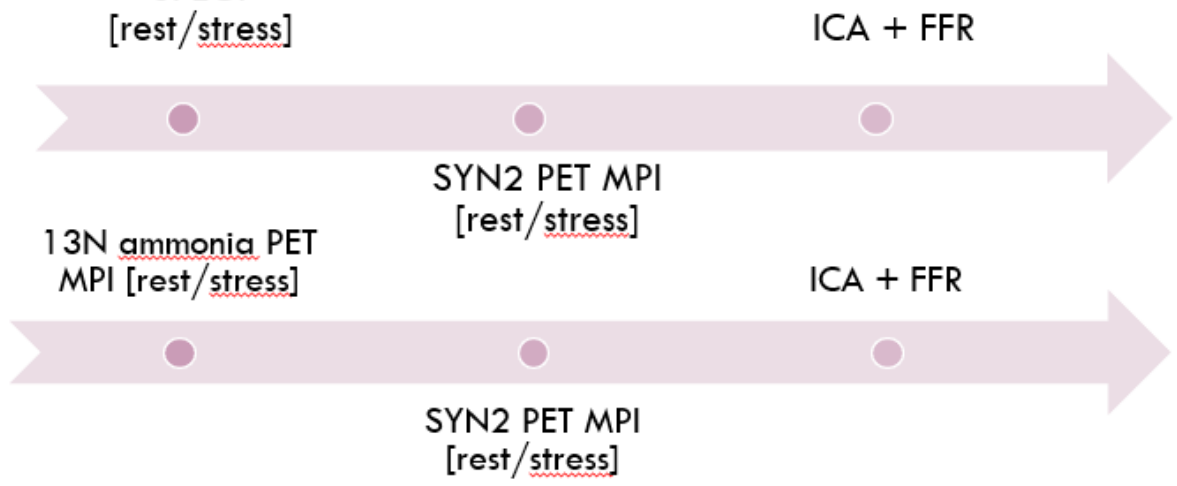
NOVEL CARDIAC TRACER FOR PET MPI – KEY FACTS

A novel 18F-labeled radiopharmaceutical developed by Synektik has successfully passed preclinical studies and Phase I/II human clinical trials. The expected advantages of this new agent over SPECT radiopharmaceuticals are improved diagnostic accuracy and image clarity. At the same time, patient exposure to ionizing radiation is lower than with SPECT.

The early-phase clinical trial was commenced after obtaining approvals from the relevant Independent Ethics Committee and Competent Authority entitled: A Phase I/II seamless, adaptive, open-label study to evaluate the safety, tolerability, radiation dosimetry, biodistribution and diagnostic ability of a novel 18F-labeled tracer, SYN2, for positron emission tomography myocardial perfusion imaging (SAFER) in healthy volunteers (Phase I) and patients with suspected coronary artery disease (Phase II).

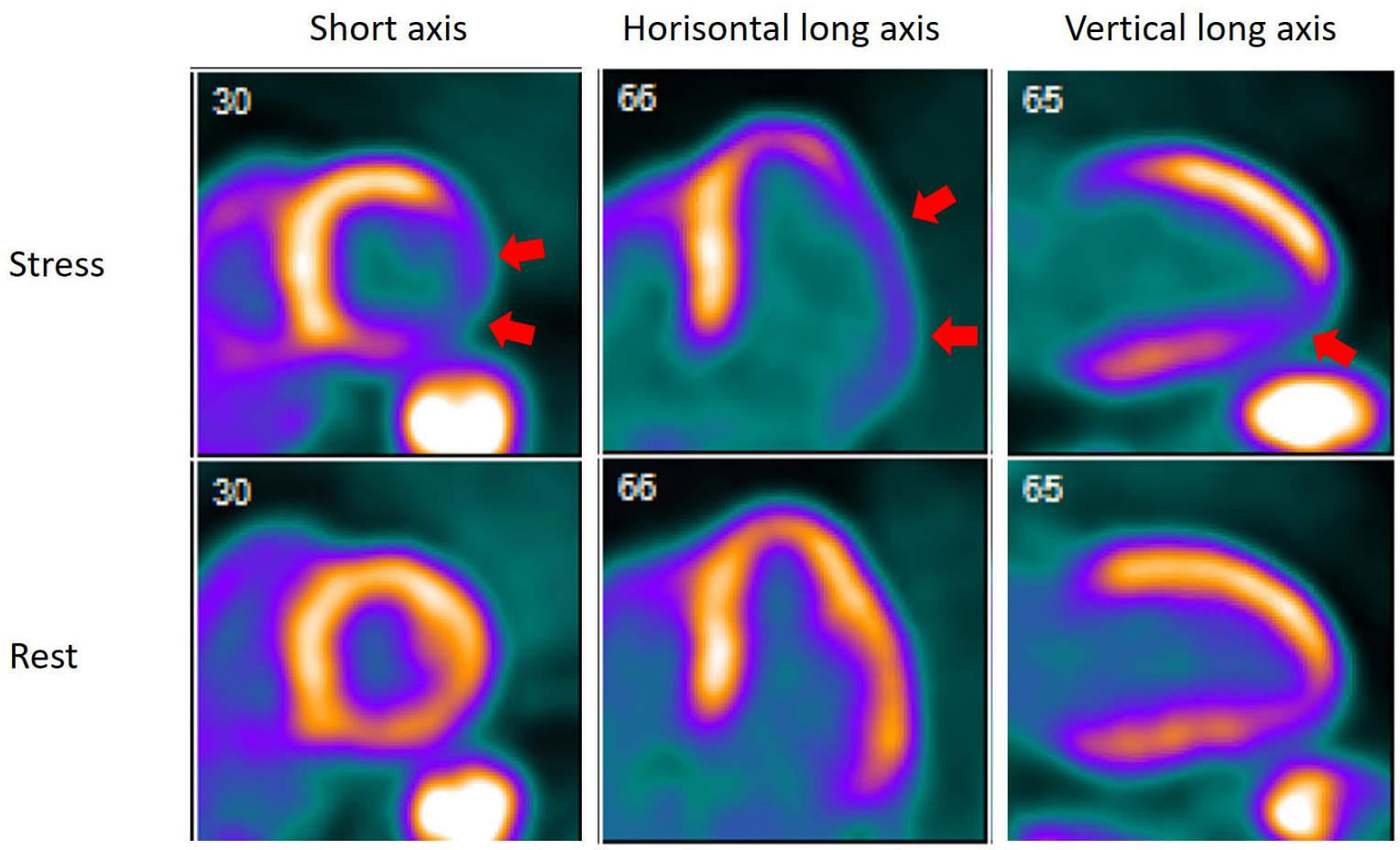
The Phase I clinical trial was conducted in Poland involving healthy adults according to the study protocol. The radiopharmaceutical demonstrated its safety profile and provided biodistribution and radiation dosing data to trigger a Phase II clinical trial involving subjects with suspected Coronary Artery Disease (CAD). The Phase II study was launched afterwards in Polish clinical sites and included patients with suspected CAD referred for Invasive Coronary Angiography (ICA). All patients underwent SPECT or PET-CT with 13N-ammonia imaging, followed by PET-CT scans with the SYN2 radiopharmaceutical.

Basic patient characteristics	
Female	52%
Male	48%
Age (range)	35-79 years
BMI (range)	20.6-44.2 kg/m2



The main objective of the Phase II clinical trial was to confirm the safety profile of SYN2 and obtain preliminary data on performance and image quality before proceeding to a large-scale international Phase III clinical trial. The Phase II clinical trial was successfully completed and the SYN2 radiopharmaceutical confirmed its safety profile: no serious adverse events related or possibly related to the SYN2 were reported in the clinical trial.

An independent panel of cardiologists read the images for diagnostic detection of obstructive CAD. The results of the resting and exercise SYN2 PET images were compared to the results of ICA with FFR.



SYN2 PET-CT sample image: Patient with obstructive coronary artery disease shows large perfusion defects in lateral, inferior and apical left ventricular wall during stress (top row). The defects were normalised at rest (lower row)

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Based on the results of the performance analysis of SYN2, Synektik observed a good image quality and promising diagnostic capabilities of the radiopharmaceutical (sensitivity, specificity and accuracy parameters of the SYN2 PET-CT imaging comparing to the ICA (with FFR) were at the high level of 75% to 80%). Due to limited population size in Phase II trial (according to the protocol), these results must be considered preliminary. The efficacy of SYN2 PET imaging will be confirmed in an international Phase III clinical trial on a larger population, that has been initiated by Synektik.