Five-Year Study Data Confirm Positive Outcomes For Patients When Abbott Diagnostic Tool Was Used To Guide Heart Stenting Decisions

- Late-breaking data presented at EuroPCR and simultaneously published in "The New England Journal of Medicine" support use of Abbott's PressureWire™ guidewire to help physicians make stenting decisions

- Stenting guided by Abbott's PressureWire diagnostic tool reduced major adverse coronary events(i), and for the first time showed that diagnostic-guided stenting plus medical therapy also resulted in fewer heart attacks over medical therapy alone

- Promising data also presented for Abbott's Resting Full-Cycle Ratio (RFR) diagnostic test that assesses the heart at rest rather than at stress

PARIS, May 22, 2018 /PRNewswire/ -- Abbott (NYSE: ABT) today announced five-year results from the FAME 2 study, which showed that patients had fewer major adverse cardiac events (MACE) when they received a heart stent guided by Abbott's fractional flow reserve (FFR) diagnostic tool in combination with medical therapy compared to patients who received only medical therapy. MACE is defined as heart attack, death and urgent need to reestablish blood flow. Abbott's PressureWire™ uses the diagnostic metric FFR to measure the pressure of blood as it flows through a patient's blocked artery. This provides an objective measure to help cardiologists determine which vessels would benefit from receiving a stent.

The five-year data from the FAME 2 study were presented in a late-breaking session at EuroPCR, the annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI) and simultaneously published in *The New England Journal of Medicine*.

"For the first time, a study has shown that patients with stable coronary artery disease who received a stent guided by an FFR diagnostic had a benefit over medical therapy alone, including fewer heart attacks and needs for urgent revascularization," said principal investigator Bernard De Bruyne, M.D., Ph.D., of the Cardiovascular Center Aalst, Onze Lieve Vrouw Ziekenhuis, Aalst, Belgium. "Data from this study confirm the importance of FFR-guided stenting decisions combined with medical therapy over medical therapy alone."

Coronary artery disease is the most common type of heart disease, which is the leading cause of death worldwide. It occurs when arteries that supply blood to the heart become blocked or narrowed. Physicians can use an FFR diagnostic tool to measure how a narrowed artery affects blood flow to the heart, and can then determine the appropriate treatment. If a narrowed artery has a positive FFR test, placing a stent via a percutaneous coronary intervention (PCI) is one recommended treatment.

Five-year follow up from the FAME 2 study included 733 patients with stable coronary artery disease who had significant blockages or narrowing of the arteries as determined by FFR. Analysis showed that 13.9 percent of patients (62) in the FFR-guided PCI group experienced a MACE, while almost twice as many patients in the medical therapy group experienced MACE (27 percent (119); p=<0.001). The lower rate of MACE in the PCI group was largely driven by reduced urgent revascularization – the need to reestablish blood flow to the heart – a component of MACE (6.3 percent vs. 21.1 percent, p<0.001).

Patients who underwent FFR-guided PCI in combination with medical therapy had fewer heart attacks than those who received medical therapy alone with 8.1 percent of patients (36) in the FFR-guided PCI group experiencing a heart attack compared to 12.0 percent (53) in the medical therapy alone group (p=0.049). Death from any cause occurred in 5.1 percent of patients in the FFR-PCI group (23) and in 5.2 percent of patients (23) in the medical therapy alone group.

Resting Full-Cycle Ratio
In a separate study presented at the meeting, promising data were presented for Abbott's Resting Full-Cycle Ratio (RFR) diagnostic test, which uses a different approach to FFR that assesses the heart at rest rather than at stress. RFR is a novel measurement that has the potential to identify significant narrowing of arteries that would be missed by other resting measures due to differences in its algorithm. RFR may be more convenient for patients than FFR as it does not require the use of vasodilators, medicines that dilate blood vessels during the test causing the heart to be stressed. The VALIDATE RFR study results were presented by Ziad Ali, M.D., D. Phil, from Columbia University Medical Center in New York.

The VALIDATE RFR study included 672 coronary artery narrowings from 504 patients and compared RFR with an instant wave-free ratio (iFR) diagnostic that also measures blood flow while the heart is at rest. The study aimed to validate the RFR algorithm, which differs from other resting measurements because it identifies critical narrowings by taking measurements across the full heart cycle.

Analysis showed RFR was highly correlated to iFR (R^2=0.99, p<0.001) and diagnostically equivalent within 1 percent to iFR (p=0.03), suggesting that both tests would lead to the same clinical decision most of the time. RFR is currently pending 510(k) and CE Mark.

"We're committed to bringing life-saving technologies to people with heart disease including diagnostic tools that help doctors make treatment decisions, which lead to better outcomes for patients," said Charles Simonton, M.D., chief medical officer of Abbott's vascular business. "These results continue to support that measuring blood flow prior to implanting a stent is an effective way to help doctors determine which vessels to treat, and can improve patient outcomes over medical therapy alone."

Important U.S. Safety Information for Abbott's PressureWire X guidewire is available at:
https://www.vascular.abbott/content/dam/bss/divisionalsites/av/products/Pressure-Wire-X-ISI.pdf

About Abbott:
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[i] MACE is defined as the need for urgent revascularization, heart attack, and death

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