Supplementary Online Content

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eAppendix 1. SOLID-TIMI 52 trial - Trial Leadership & Investigators

eAppendix 2. Inclusion and Exclusion Criteria

eAppendix 3. Clinical Endpoint Definitions

eFigure 1. Cumulative Incidence Curves for the Secondary Endpoint CV Death, MI or Stroke

eFigure 2. Subgroups of Interest for the Secondary Composite Endpoint of CV Death, MI or Stroke

eTable. Summary of MI According to the Universal Classification of MI by Randomized Treatment Arm

eReferences

This supplementary material has been provided by the authors to give readers additional information about their work.

eAppendix 1. SOLID-TIMI 52 trial - Trial Leadership & Investigators

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Israel
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Netherlands
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Poland
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Spain
Barrabes Riu, José Antonio, Figueras Bellot, Jaume (FPI), Hospital Vall De Hebron, Barcelona (25); Bayón Fernández, Julián, Simarro Martin-Ambrosio, Eugenio (FPI), Hospital de Leon, León (6); Benedicto Buendía, Amparo, Hospital de la Princesa, Madrid (5); Castro Conde, Almudena, Hospital la Paz, Madrid (24); Íñiguez Romo, Andrés, Hospital de Meixoeiro, Vigo/Pontevedra (5); Jiménez Navarro, Manuel, Hospital Clinico Universitario Virgen Victoria, Malaga (21); López García-Aranda, Víctor, Hospital Vírgen de la Macarena, Sevilla (13); Mainar Tello, Vicente, Hospital General Universitario de Alicante, Alicante (24); Marco Garde, Pilar, Hospital de Donostia, San Sebastián (10); Mayordomo López, Juan, Hospital Central de Asturias, Oviedo (11); Mollá Jimenez, Cristina, Antón Pascual, Jose Luis (FPI), Mollá Jimenez, Cristina (FPI), Hospital de San Juan, San Juan/Alicante (2); Plaza Pérez, Ignacio, Hospital Infanta Sofía, San Sebastián de los Reyes/Madrid (3); Ridocci Soriano, Francisco, Hospital General de Valencia, Valencia (6); Viles Beltrán, Dolors, Hospital Arnau de Vilanova, Lerida, Lerida (11).

Sweden
Bandh, Stellan, Centrallasarettet Västerås, Västerås (25); Christensen, Kjeld, Universitetssjukhuset i Örebro, Örebro (12); Dellborg, Mikael, Sahlgrenska Universitetssjukhuset/ Östra, Göteborg (19); Herlitz, Johan, Sahlgrenska Universitetssjukhuset, Göteborg (22); Karlsson, Jan-Erik, Länssjukhuset Ryhov, Jönköping (27); Mooe, Thomas, Östersunds Sjukhus, Östersund (16); Persson, Birgitta, Sahlgrenska Universitetssjukhuset/ Mölndal, Göteborg (20); Timberg, Ingar, Hässleholms Sjukhus, Hässleholm (4); Witt, Nils, Södersjukhuset, Stockholm (12).

Taiwan
Chen, Shih-Ann, Taipei Veterans General Hospital, Taipei (18); Cheng, Chen-Chuan, Chi Mei Medical Center, Yung Kang City (6); Hung, Huei-Hong, Shin Kong Wu Ho-Su Memorial Hospital, Taipei (13); Lai, Wen-Ter, Kaohsiung Medical University Hospital, Kaohsiung City (5); Tu, Chung-Ming, Li, Ai-Hsien (FPI), Wu, Ching-Fen (FPI), Far Eastern Memorial Hospital, Taipei (12); Wu, Chiung-Jen, Chang Gung Memorial Hospital- Kaoshiung, Kaohsiung (70); Yin, Wei-Hsian, Cheng Hsin Rehabilitation Medical Center, Taipei (6).

Thailand
Buakhamsri, Adisai, Thammasat University Hospital, Pathumthani (2); Kaewsuwanna, Pinij, Maharat Nakhonratchasima Hospital, Nakhon Ratchasima (15); Kiatchoosakun, Songsak, Khon Kaen University, Khon Kaen, Muang (24); Kuanprasert, Srun, Maharajnakorn Chiangmai Hospital, Chiangmai (39);

Sritara, Piyamitr, Ramathibodi Hospital, Mahidol University, Bangkok (15); Wongpraparut, Nattawut, Siriraj Hospital, Bangkoknoi (19).

Turkey
Bayata, Serdar, Ministry of Health Izmir Ataturk Training and Research Hospital, Izmir (5); Guneri, Sema, Dokuz Eylul University Medical Faculty, Izmir (3); Yavuzgil, Oguz, Ege University Medical Faculty, Izmir (1).

Ukraine
Amosova, Ekaterina, Olexandrivska Clinical Hospital, Kyiv (13); Batushkin, Valerii, Kiev City Hospital #5,, Kyiv (18); Dyadyk, Oleksandr, Donetsk National Medical University n.a. M. Horkyy, Donetsk (6); Goloborodko, Borys, Odesa City Clinical Hospital #3, Odesa (6); Karpenko, Oleksandr, Kyiv City Clinical Hospital No. 1, Kyiv (10); Kononenko, Lyudmyla, City Clinical Hospital #27, Kharkiv (9); Kopytsya, Mykola, Institute of Therapy at Academy of Med. Sciences, Kharkiv (8); Koval, Olena, Dnipropetrovsk City Emergency Joint Hospital, Dnipropetrovsk (15); Kovalskyy, Ihor, Mykolayiv City Hospital #1, Mykolaiv (15); Legkonogov, Olexandr, Simferopol City Emergency Hospital #6, Simferopol (19); Malynovsky, Yaroslav, Shershnyova, Oxana (FPI), Municipal Institution Regional Cardiology Dispensary, Zaporizhzhya (12); Netiazhenko, Vasyl, National Medical University named after O. Bogomolets, Kyiv (9); Nikonov, Vadim, City Clinical Emergency Hospital n.a. Meshchaninov, Kharkiv (3); Parkhomenko, Oleksandr, Institute of Cardiology named after Strazhesko, Kyiv (7); Prokhorov, Oleksandr, City Clinical Hospital No 27, Kharkiv (9); Rebrov, Borys, Potapenko, Pavlo (FPI), MI Lugansk SMU Ch of Internal Medicine with Professional Pathology and Therapeutic Exercise, Lugansk (15); Rudenko, Leonid, Kyiv Clinical Emergency Care Hospital, Kyiv (28); Shcherbak, Viktor, Vinnytsia City Clinical Hospital #1, Vinnytsia (56); Stanislavchuk, Mykola, Vinnytsya National Medical University n.a. M.I. Pyrohov, Vinnytsia (21); Tseluyko, Vira, City Clinical Hospital # 8, Kharkiv (10); Yagensky, Andriy, Lutsk City Hospital, Lutsk (17).

United Kingdom
Ahsan, Arif, Nottingham City Hospital, Nottingham, Nottinghamshire (6); Been, Martin, University Hospital Coventry, Coventry, West Midlands (11); Bethell, Hugh, Senior, Roxy (FPI), Northwick Park Hospital, Harrow, Middlesex (6); Cox, Dominic, Northampton General Hospital, Northampton, Northamptonshire (17); Findlay, Iain, Royal Alexandra Hospital, Paisley (7); Fisher, Michael, Royal Liverpool University Hospital, Liverpool (18); Gandhi, Manish, Royal Devon and Exeter Hospital, Exeter, Devon (14); Gorog, Diana, Queen Elizabeth II Hospital, Hertfordshire (9); Jacques, Adam, St Peter's Hospital, Chertsey, Surrey (4); Keeling, Philip, Torbay Hospital, Torquay, Devon (26); O'Rourke, Brian, Hairmyres Hospital, East Kilbride (8); Pell, Alastair, Monklands Hospital, Airdrie, Lanarkshire (10); Spratt, James, NHS Forth Valley,Stirling Royal Infirmary, Stirling (20); Trouton, Thomas, Antrim Area Hospital, Antrim (1); Wong, Yuk-ki, St Richard's Hospital, Chichester (11).

United States
Abadier, Rafik, Nature Coast Clinical Research LLC, Inverness, Florida (2); Abrahams, Lisa, Duluth Clinic, St. Mary's Medical Center, Duluth, Minnesota (8); Afonso, Luis, Wayne State University, Detroit, Michigan (8); Aggarwal, Atul, Central Cardiology Medical Clinic, Bakersfield, California (6); Aggarwal, Kul, University of Missouri Health Care, Columbia, Missouri (20); Ahmed, Abdel, Altru Health System, Grand Forks, North Dakota (9); Ahmed, Syed, McLaren Regional Medical Center, Flint, Michigan (6); Albirini, Abdulhay, Genesis Healthcare System, Zaneville, Ohio (11); Anderson, Jay, Internal Medical Associates, Grand Island, Nebraska (4); Angiolillo, Dominick, University of Florida Health Science Center, Jacksonville, Florida (11); Ansari, Saadat, Saadat Ansari. MD office, Huntsville, Alabama (1);

Applegate, Robert, Wake Forest University School of Medicine, Winston-Salem, North Carolina (7); Arif, Imran, Leesar, Massoud (FPI), University Internal Medicine Associates, Cincinnati, Ohio (6); Aronow, Herbert, Michigan Heart PC, Ypsilanti, Michigan (17); Asbill, Brian, Asheville Cardiology Associates, Asheville, North Carolina (59); Ashraf, Raashid, Cardiovascular Associates of The Southeast, LLC, Birmingham, Alabama (5); Atalay, Hasan, Capital Cardiology Associates, Albany, New York (4); Atassi, Keith, Northwest Indiana Cardiovascular Physicians, Valparaiso, Indiana (7); Atieh, Mahmoud, Sanford Cardiology, Sanford, North Carolina (2); Babayan, Zaruhi, Harjai, Kishore (FPI), Guthrie Healthcare System, Sayre, Pennsylvania (13); Baker, Seth, Indian River Cardiology Associates, Vero Beach, Florida (7); Barr, Lawrence, Midwest Heart Foundation, Oakbrook Terrace, Illinois (12); Barringhaus, Kurt, University of Massachusetts, Worcester, Massachusetts (26); Bayron, Carlos, Interventional Cardiac Consultants, Trinity, Florida (5); Benjamin, Sabrina, Universal Research Group, Tacoma, Washington (4); Benton, Robert, Capital Cardiology, Troy, New York (11); Berglund, Robert, Conn, Eric (FPI), Chattanooga Heart Institute, Chattanooga, Tennessee (5); Bertolet, Barry, Cardiology Associates Research, LLC, Tupelo, Mississippi (8); Bhagwat, Ravi, Cardiology Associates of Northwest Indiana, Hammond, Indiana (26); Biederman, Robert, Allegheney General Hospital, Pittsburgh, Pennsylvania (6); Bisher, Edward, Baptist Heart Specialists, Jacksonville, Florida (3); Blanchard, Arnoux, Comprehensive Care Center/ North Broward Hospital District, Fort Lauderdale, Florida (9); Brown, Christopher, The Heart Group - Mobile, Mobile, Alabama (16); Butman, Samuel, Heart and Vascular Center of Northern Arizona, Cottonwood, Arizona (9); Campbell, Charles, University of Kentucky Gill Heart Institute, Lexington, Kentucky (11); Canaday, Donald, Inland Cardiology Associates of Spokane, Spokane, Washington (9); Carlson, Thomas, Austin Heart, PA, Austin, Texas (9); Casale, Paul, Lancaster General Hospital, Lancaster, Pennsylvania (6); Cashion, Jr, William, Austin Heart P.L.L.C, Harker Heights, Texas (12); Chandler, Arthur, Chandler Cardiovascular Clinical Research LLC, Augusta, Georgia (4); Chandna, Harish, Victoria Heart and Vascular Center, Victoria, Texas (10); Chandrasekaran, Suresh, Midwest Regional Medical Center, Midwest City, Oklahoma (1); Chang, George, Chronos, Nicolas (FPI), Saint Josephs Hospital of Atlanta, Atlanta, Georgia (14); Chang, Mark, Center for Cardiovascular Research, Johnson City, Tennessee (14); Chhabra, Anil, Cardiovascular Research, LLC, Shreveport, Louisiana (7); Chin, John, Mercy Heart and Vascular Institute, Sacramento, California (11); Cochran, David, St. John's Health System, Springfield, Missouri (10); Cohen, Kenneth, New West Physicians, PC, Golden, Colorado (9); Cucher, Fred, Phoenix Heart Cardiovascular Center, Glendale, Arizona (4); Dauber, Ira, South Denver Cardiology, Littleton, Colorado (8); De Gregorio, Michele, Saint Joseph Mercy-Oakland, Pontiac, Michigan (9); Del Core, Michael, Creighton Cardiac Center, Omaha, Nebraska (8); Dewhurst, Robert, Rodriguez, Rolando (FPI), Bay Area Cardiology Associates, P.A., Brandon, Florida (7); Dionisopoulos, Peter, Nebraska Heart Institute, Lincoln, Nebraska (5); Donovan, Daniel, Cardiology Clinic of San Antonio, San Antonio, Texas (20); Doty, William, Cardiology Consultants, Pensacola, Florida (7); Drossner, Michael, Midatlantic Cardiovascular Associates, P.A., Bel Air, Maryland (6); East, Cara, Soltero CV Research Center, Dallas, Texas (31); Eaton, Gregory, Mid Ohio Heart Clinic, Mansfield, Ohio (1); Ebrahimi, Ramin, West Los Angeles VAMC, Los Angeles, California (4); Effron, Barry, University Hospitals of Cleveland, Cleveland, Ohio (4); Elkhadra, Maan, JHS Hospital of Cook County, Chicago, Illinois (2); Elsner, Gregory, St. Vincent Medical Grp, Inc, Indianapolis, Indiana (7); Erickson, Bernard, Central MN Heart Center at St Cloud Hospital, St Cloud, Minnesota (10); Fehrenbacher, George, Roseville Cardiology Medical Associates, Roseville, California (5); Feldman, Robert, Mediquest Research Group, INC, Ocala, Florida (11); Fernandes, Valerian, RHJ

VA Medical Center, Charleston, South Carolina (13); Fishberg, Robert, Overlook Hospital, Summit, New Jersey (11); Flores, Angel, Heritage Vly Med Grp, Inc. d/b/a The Heart & Vascular Ctr, Beaver, Pennsylvania (10); Foreman, Riley, St. Edward Mercy Medical Center Clinical Research, Fort Smith, Arkansas (2); Frankel, Robert, Maimonides Medical Center Faculty Practice Plan, Brooklyn, New York (1); French, William, Harbor - UCLA Medical Center, Torrance, California (7); Fuentes, Francisco, Herman Hospital, Houston, Texas (6); Fujise, Kenichi, University of Texas Med. Branch, Galveston, Texas (10); Fulmer, James, River City Clinical Research, Jacksonville, Florida (9); Gabry, Mark, Baig, Mirza (FPI), Curran, Patrick (FPI), New England Center for Clinical Research, Fall River, Massachusetts (8); Garcia Pulido, Jesus, Jacksonville Cardiovascular Center, Jacksonville, Florida (11); Gatien, Lionel, Fleming Island Center for Clinical Research, Fleming Island, Florida (9); Gazmuri, Raul, North Chicago VA Medical Center, North Chicago, Illinois (4); Gencheff, Nelson, Upper Michigan Cardiovascular Associates, PC, Marquette, Michigan (1); Gilmore, Richard, Imperial Health, Lake Charles, Louisiana (10); Giugliano, Gregory, Baystate Medical Center, Springfield, Massachusetts (9); Goldberg, Ronald, La Mesa Cardiac Center, La Mesa, California (12); Goldman, Steven, Movahed, M. Reza (FPI), Southern Arizona VA Health Care System, Tucson, Arizona (1); Goldstein, Mark, Chesapeake Cardio Vascular Associates, Townson, Maryland (17); Gonzalez, Domingo, Houston Metropolitan Cardiology Associates, LLC, Houston, Texas (11); Gottlieb, Daniel, Daniel W. Gottlieb, MD, PS, Burien, Washington (1); Grabarczyk, Mark, Upstate Cardiology PA, Greenville, South Carolina (20); Graham, Bruce, Medical Consultants, Muncie, Indiana (20); Gruberg, Luis, Stony Brook University Medical Center, Stony Brook, New York (13); Gumm, Darrel, Heart Care Midwest, Peoria, Illinois (8); Gupta, Saurabh, Lee, David (FPI), Oregon Health Sciences University, Portland, Oregon (1); Hage-Korban, Elie, Heart and Vascular Centre of West TN, Jackson, Tennessee (18); Hakas, Joseph, Pinehurst Medical Clinic, Inc., Pinehurst, North Carolina (15); Hamroff, Glenn, NYU Hudson Valley Cardiology, Cortlandt Manor, New York (27); Harris, Barry, Sunrise Clinical Research, Hollywood, Florida (9); Hearne, Steven, Delmarva Heart Diagnostic Center, Salisbury, Maryland (9); Held, John, Fairfield Cardiac Cath Lab Research Center, Fairfield, Ohio (4); Henderson, David A., Cardiology Research Associates, Daytona Beach, Florida (24); Hermany, Paul, Buxmont Cardiology Associates, Sellersville, Pennsylvania (5); Herzog, William, Johns Hopkins University, Columbia, Maryland (5); Hinchman, David, Fry, Stefanie (FPI), Saint Lukes Idaho Cardiology Associates, Boise, Idaho (11); Hockstad, Eric, Kansas City Heart Foundation, kansas City, Missouri (5); Hodson, Robert, The Oregon Clinic, Portland, Oregon (9); Hollenbaugh, Darren, Spokane Cardiology, Spokane, Washington (12); Horwitz, Phillip, University of Iowa Hospitals and Clinics, Iowa City, Iowa (16); Hurst, Paul, North Colorado Medical Center, Greeley, Colorado (1); Ibrahim, Hassan, North Ohio Research, Ltd, Sandusky, Ohio (14); Imburgia, Michael, Louisville Cardiology Medical Group, Louisville, Kentucky (18); Izzo, Mark, Consultants in Cardiovascular Disease, Inc., Erie, Pennsylvania (11); Jaffrani, Naseem, Alexandria Cardiology Clinic, Alexandria, Louisiana (6); Jan, Mian, West Chester Cardiology, West Chester, Pennsylvania (7); Janout, Marek, Ring, Michael (FPI), Heart Clinics Northwest, Spokane, Washington (25); Jones, Steven, Cardiovascular Associates of The Southeast, LLC, Birmingham, Alabama (7); Kahn, Brian, Overlea Personal Physician, Baltimore, Maryland (2); Kakavas, Peter, Heart Care Research Foundation, Mokena, Illinois (1); Kates, Andrew, Bach, Richard (FPI), Washington University School of Medicine, St Louis, Missouri (16); Katopodis, John, Tallahassee Research Institute, Tallahassee, Florida (13); Kazimir, Michal, Drogue Medical LLC, Wheat Ridge, Colorado (6); Kennett, Jerry, Missouri Cardiovascular Specialists, Columbia, Montana (19); Kereiakes, Dean, Carl and Edyth Lindner Center for Research and Education at the Christ Hospital,

Cincinnati, Ohio (20); Kersh, Robert, Cardio Pulmonary Associates, Plantation, Florida (6); Kershner, Dawn, Meilman, Henry (FPI), Midatlantic Cardiovascular Associates PA, Baltimore, Maryland (3); Kerwin, Peter, Midwest Heart Foundation, Oakbrook Terrace, Illinois (10); Khera, Amit, University of Texas Southwestern Medical Center at Dallas, Dallas, Texas (5); Kieval, Joshua, ZASA Clinical Research, Atlantis, Florida (6); Kim, Edward, Eastside Cardiology Associates, Kirkland, Washington (4); Kobayashi, John, Nelson, Ronald (FPI), Cardiology Associates Inc., South Bend, Indiana (5); Kosinski, Edward, Connecticut Clinical Research, Bridgeport, Connecticut (10); Kovacich, David, Indiana Heart Physcian, Indianapolis, Indiana (6); Kraft, Philip, William Beaumont Hospital, Troy, Michigan (13); Kramer, Jeffrey, Cardiovascular Associates of the Delaware Valley, Sewell, New Jersey (1); Kruse, Kevin, Sanger Heart &. Vascular Institute, Concord, North Carolina (1); Kuvin, Jeffrey, Tufts Medical Center, Boston, Massachusetts (10); Labib, Atef, Humility of Mary Health Partners, Youngstown, Ohio (2); Labroo, Ajay, Advanced CardioVascular Consultants, SC, Rock Island, Illinois (5); Langer, Michael, North Ohio Research, Ltd., Elyria, Ohio (2); Lau, Theodore, Franciscan Health System Research Center, Tacoma, Washington (8); Lee, Kwan, Movahed, M. Reza (FPI), University of Arizona Medical Center, Tucson, Arizona (11); Lee, Tobias, Multicare Health System, Tacoma, Washington (15); Levite, Howard, AtlantiCare Regional Medical Center, Pomona, New Jersey (10); Lewis, David, Wisconsin Heart, SC, Madison, Wisconsin (9); Lieber, Ira, Texas Cardiology Research Center, Kingwood, Texas (15); Loh, Irving, Westlake Medical Research, Westlake Village, California (6); Lopez, Mario, Charlotte Cardiac Research Center, Port Charlotte, Florida (20); Lui, Henry, Research Associates of Jackson, Jackson, Tennessee (28); Malkowski, Michael, Heritage Valley Medical Group, Inc, Leetsdale, Pennsylvania (3); Mammen, George, Katy Internal Medicine Associates, Katy, Texas (10); Mascolo, Richard, Central Bucks Cardiology, Doylestown, Pennsylvania (3); Matsumura, Martin, Lehigh Valley Hospital and Health Network, Allentown, Pennsylvania (9); Matthews, George, Corbelli, John (FPI), Buffalo Cardiology and Pulmonary Associates, Williamsville, New York (6); Mayer, Thomas, North Shore Cardiovascular Research Consortium, Bannockburn, Illinois (2); McAlhany, Christopher, Lebauer Cardiovascular Research Foundation, Greensboro, North Carolina (27); McCullum, Kevin, York Hospital Wellspan, York, Pennsylvania (19); Meholick, Alan, Buffalo Heart Group, Buffalo, New York (9); Mehta, Viral, Comprehensive Cardiovascular Medical Group, Bakersfield, California (12); Melhado, Mauricio, Cardiology Partners, Wellington, Florida (13); Menees, Daniel, University of Michigan, Ann Arbor, Michigan (4); Miller, Michael, University Maryland Hospital, Baltimore, Maryland (1); Minisi, Anthony, McGuire VA Medical Center, Richmond, Virginia (4); Minor, Steven, Austin Heart, San Marcos, Texas (3); Moore, Carl, Nygaard, Thomas (FPI), Stroobants Cardiovascular Center, Lynchburg, Virginia (16); Morcos, Nabil, Apex Research Institute, Santa Ana, California (1); Morris, Pamela, Medical University of South Carolina, Charleston, South Carolina (1); Morrow, David, Brigham & Women's Hospital, Boston, Massachusetts (4); Mostel, Edward, Palm Beach Gardens Research Center, LLC, Palm Beach Gardens, Florida (8); Murdock, David, Aspirus Heart & Vascular Inst. (AHVI)-Rsrch & Edu, Wausau, Wisconsin (9); Nadar, Venkatesh, Capital Area Research LLC, Camp Hill, Pennsylvania (6); Nahhas, Ahed, The Toledo Hospital, Toledo, Ohio (1); Navas, Jorge, Clearwater Cardiovascular and Interventional Consultants, Clearwater, Florida (8); Nukta, Emad, Cleveland Cardiovascular Research Foundation, Fairview Park, Ohio (4); Oberoi, Mandeep, Central Jersey Health Care, Trinitas Hospital, Elizabeth, New Jersey (21); O'Donnell, Philip, Winchester Medical Center, Winchester, Virginia (31); Ostfeld, Robert, Montefiore Medical Center, Bronx, New York (12); Pacheco, Theodore, North Ohio Research, LTD, Lorain, Ohio (3); Panchal, Vipul, Norton Cardiovascular Associates, Louisville,

Kentucky (14); Parang, Pirouz, Deborah Heart, Browns Mills, New Jersey (10); Paraschos, Alexander, Kernodle Clinic, Inc., Burlington, North Carolina (16); Pasquini, John, Williams Jr, Jerome (FPI), Novant Health Heart and Vascular Institute, Charlotte, North Carolina (28); Patlola, Raghotham, Cardiovascular Institute of the South, Lafayette, Louisiana (1); Peart, Brenda, Southwest Heart Group, LLC, Tucson, Arizona (12); Penny, William, UCSD/San Diego VA Medical Center, San Diego, California (6); Pepine, Carl, University of Florida, Gainesville, Florida (15); Perlman, Richard, Pavlides, Andreas (FPI), Associated Cardiovascular Consultants PA, Cherry Hill, New Jersey (13); Popeil, Larry, Magnolia Research Group Inc., Ocala, Florida (2); Prashad, Rakesh, Ocala Research Institute, Ocala, Florida (4); Price, Daniel, Cardiology Associates of New Haven, P.C., Guilford, Connecticut (10); Price, Robert, Mid Carolina Research, Matthews, North Carolina (11); Puleo, Peter, St. Lukes Health Network, Bethlehem, Pennsylvania (8); Puri, Sanjeev, Trinity Medical Center, Rock Island, Illinois (14); Raikhel, Marina, Torrence Clinical Research, Lomita, California (6); Ramachandran, Atul, Midlands Hospital, Papillion, Nebraska (6); Ramos, Mark, Concha, Mauricio (FPI), Intercoastal Medical Group, Sarasota, Florida (10); Randhawa, Preet, NJ Heart Research, Linden, New Jersey (21); Reichek, Nathaniel, St. Francis Hospital-Research Dept, Roslyn, New York (4); Riba, Arthur, Oakwood Hospital & Medical Center, Dearborn, Michigan (5); Ricciardi, Mark, University of New Mexico Health Sciences Center, Albuquerque, New Mexico (2); Rider, James, Fenton, Sarah (FPI), Cardiology Associates of Green Bay, LTD, Green Bay, Wisconsin (18); Rizvi, Mohammad Ali, Dahiya, Ranjan (FPI), Regions Hospital, Saint Paul, Minnesota (11); Rogers, William, University Of Alabama At Birmingham, Birmingham, Alabama (42); Roth, David, Glacier View Cardiology, Kalispell, Montana (2); Rowe, William, Great Falls Clinic, LLP, Great Falls, Montana (3); Saba, Fadi, Professional Health Care, St. Petersburg, Florida (6); Sabri, Moustafa, Patel, Parag (FPI), Advocate Lutheran General Hospital, Park Ridge, Illinois (9); Sandoval, Jaime, Padre Coast Medical Associates, Corpus Christi/Texas, Texas (3); Sangrigoli, Renee, Doylestown Cardiology Associates-VIAA, Doylestown, Pennsylvania (13); Schwartzbard, Arthur, New York University, New York, New York (4); Seidner, Michael, Green and Seidner Family Practice, Landsdale, Pennsylvania (4); Shah, Anil, Coastal Multi-Specialty Research, Santa Ana, California (15); Shanes, Jeffrey, Consultants in Cardiovascular Medicine, Melrose Park, Illinois (7); Sharma, Mukesh, Parkway Cardiology Associates, Oak Ridge, Tennessee (11); Siegel, Craig, Austin Heart, Round Rock, Texas (10); Singal, Dinesh, Cardio Metabolic Institue, Somerset, New Jersey (8); Singh, Narendra, Atlanta Heart Specialists, Cumming, Georgia (23); Smith, Andrew, Panetta, Carmelo (FPI), Park Nicollet Heart and Vascular Center, Minneapolis, Minnesota (2); Smith, Steven, Whitaker, Jack (FPI), Mountain States Health Alliance, Johnson City, Tennessee (1); Snell, Jeffrey, Rush University Medical Center, Chicago, Illinois (4); Snyder, Harvey, Cardiovascular Associates of the Delaware Valley, Haddon Heights, New Jersey (2); Soffer, Ariel, Soffer Heart Institute, Aventura, Florida (1); Sonel, Ali, VA Pittsburgh Healthcare System, Pittsburgh, Pennsylvania (3); Spencer, Robert, Cardiology Consultants, Pensacola, Florida (14); Staniloae, Cezar, Gotham Cardiovascular Research, PC, New York, New York (9); Stephenson, Christopher, Novant Health Heart and Vascular Institute, Monroe, North Carolina (6); Sundaram, Senthil, Raleigh Cardiology Associates, Raleigh, North Carolina (15); Sutton, Laddeus, Letts, Dustin (FPI), Mid Carolina Research, Gastonia, North Carolina (23); Swint Sr., Robert, Lutheran Hospital, Fort Wayne, Indiana (2); Tallet, Julio, South Florida Research Solutions, LLC, Miramar, Florida (14); Tami, Luis, Research Physicians Network Alliance, Hollywood, Florida (5); Taylor, Richard, Hanovich, Gary (FPI), North Memorial Medical Health Center, Robbinsdale, Minnesota (2); Tedder, Barry, Cardiology Associates of Northeast Arkansas, Jonesboro, Arkansas (13); Teufel, Edward, Brett, Craig (FPI),

Cardiovascular Consultants of Maine, Scarborough, Maine (9); Thomas, James, Medical University of South Carolina, Charleston, South Carolina (7); Thompson, Paul, Polk, Donna (FPI), Hartford Hospital, Hartford, Connecticut (6); Tilkian, Ara, Providence Holy Cross Medical Center, Mission Hills, California (4); Tinkel, Jodi, Pandya, Utpal (FPI), University of Toledo, Toledo, Ohio (11); Tobiansky, Joel, The Dayton Heart Center, Dayton, Ohio (8); Trippi, James, The Care Group, Avon, Indiana (2); Tuohy, Edward, Bridgeport Hospital, Bridgeport, Connecticut (7); Uretsky, Barry, Central Arkansas Veterans Healthcare System, Little Rock, Arkansas (5); Uusinarkaus, Kari, Colorado Springs Health Partners, Colorado Springs, Colorado (1); Varma, Shalendra, Boice-Willis Clinic, P.A., Rocky Mount, North Carolina (5); Velasquez, Enrique, The Heart Center, Huntsville, Alabama (30); Vogel, Craig, Cardiovascular Medical Specialists of the Palm Beaches, Jupiter, Florida (8); Voyce, Stephen, Advanced Cardiology Specialists, Scranton, Pennsylvania (18); Wainwright, William, Hancock, Holly (FPI), Baptist Heart Specialists, Jacksonville Beach, Florida (6); Walder, James, Black Hills Clinical Research Center, Rapid City, South Dakota (34); Wali, Andreas, Holy Spirit Hospital, Camp Hill, Pennsylvania (11); Watkins, Stanley, Alaska Heart Institute, Anchorage, Alaska (3); Weiss, Robert, Central Marine Heart and Vascular Institute, Lewiston, Maine (8); Wickemeyer, William, Iowa Heart Center, PC, West Des Moines, Iowa (18); Wilson, Dennis, Novant Health Heart and Vascular Institute, Salisbury, North Carolina (4); Wilson, Vance, Daytona Heart Group, Daytona Beach, Florida (22); Wiseman, Alan, Northeast Cardiology Assocaites, Bangor, Maine (33); Wright, Jr., William, Esse Health Cardiology Consultants, St.Louis, Missouri (6); Xenakis, Mark, Cardiovascular Associates of Virginia, Midlothian, Virginia (1); Zelenka, Jason, Clearwater Cardiovascular and Interventional Consultants, Safety Harbor, Florida (23); Zilz, Nathan, Amidon, Thomas (FPI), Hope Heart Institute, Bellevue, Washington (16).

eAppendix 2. Inclusion and Exclusion Criteria

a) Inclusion criteria

1. Signed written informed consent prior to beginning study-related procedures.
2. Male or female aged at least 18 years, inclusive, at randomization. Female subjects must be post-menopausal or using a highly effective method for avoidance of pregnancy.
3. Hospitalization for ACS (unstable angina, non-ST segment elevation MI, or ST segment elevation MI) ≤30 days prior to randomization:
a. Unstable angina (UA) is defined as ischemic chest discomfort (or equivalent) that occurs at rest with at least 1 episode lasting ≥10 minutes and is accompanied by new or presumably new ST segment deviation (transient [<20 minutes] elevation ≥0.1mV or dynamic horizontal/down-sloping depression ≥0.05mV) in at least 2 contiguous leads without diagnostic biochemical changes in cardiac enzymes (serum troponin I or T, or creatine kinase-MB).
b. Non-ST segment elevation MI (NSTEMI) is defined as ischemic chest discomfort (or equivalent) that occurs at rest with at least 1 episode lasting ≥10 minutes and is accompanied by a diagnostic elevation in cardiac biomarkers of myocardial injury (serum troponin I or T, or creatine kinase-MB) above the upper limit of normal without persistent ST segment elevation.
c. ST segment elevation MI (STEMI) is defined as prolonged symptoms of ischemic chest discomfort (or equivalent) at rest (with at least 1 episode lasting >20 min) and new or presumably new electrocardiographic changes (persistent ST segment elevation ≥0.1 mV in ≥2 contiguous precordial leads or ≥2 adjacent limb leads or new LBBB) that are accompanied by a diagnostic elevation in cardiac biomarkers (serum troponin I or T, creatine kinase or creatine kinase-MB) above the upper limit of normal.
4. The subject must be clinically stable for 24 hours prior to randomization
5. For subjects in whom a percutaneous coronary intervention (PCI) is planned as part of management for the qualifying ACS event, the subjects should undergo PCI prior to randomization whenever possible.

b) Additional predictors of cardiovascular risk

All subjects must also have at least one of the following high-risk predictors:
a. age ≥60 years at randomization.
b. history of documented MI prior to qualifying ACS event.
c. diabetes mellitus requiring pharmacotherapy.
d. significant renal dysfunction (defined as estimated glomerular filtration rate [eGFR] ≥30 and ≤59 mL/min/1.73 m^2), according to MDRD equation.
e. polyvascular disease manifested in this ACS population as coexistent clinically diagnosed arterial disease in at least 1 peripheral arterial territory, defined as: • cerebrovascular disease defined as carotid artery disease,[1] or as prior ischemic stroke[2] that occurred >3 months prior to randomization. OR • peripheral arterial disease (PAD) [3].

[1] Carotid disease is defined as unilateral or bilateral carotid stenosis >60% OR history of carotid surgery or stenting.

[2] Prior ischemic stroke is defined as documented focal neurologic deficit thought to be of vascular origin, with signs or symptoms lasting >24 hours. It is strongly recommended that neuroimaging, such as computed tomography (CT) scan or magnetic resonance imaging (MRI) be performed to confirm diagnosis. In the absence of neuroimaging, additional functional deficit must be documented by abnormalities in the modified Rankin Score.

[3] PAD is documented by one of the following: current intermittent claudication with objective evidence of vascular origin, history of peripheral arterial stenting or surgery (including amputation due to vascular causes), or ankle-brachial index <0.9 in at least one ankle.

c) Exclusion criteria

Subjects meeting any of the following criteria must not be enrolled in the study:
1. Clinical or laboratory manifestations of ACS that is not believed to be thrombotic in origin or is believed to be secondary to other apparent illness.
2. Absence of obstructive coronary artery disease (i.e., at least one stenosis [>50%] in a major vessel, major branch or bypass graft) based on angiography, if performed, between the time of presentation with ACS and randomization.
3. Planned coronary artery bypass graft (CABG) surgery or CABG surgery performed following the qualifying event and prior to randomization.
4. Cirrhosis, known biliary abnormalities (with the exception of Gilbert's syndrome or asymptomatic gallstones), unstable liver disease, or evidence of abnormal liver function tests (total bilirubin or alkaline phosphatase >1.5 x upper limit of normal [ULN]; or ALT >2.5 x ULN) or other hepatic abnormalities that in the opinion of the investigator would preclude the subject from participation in the study.
5. Severe renal impairment (e.g., patients with an eGFR <30 mL/min/1.73 m^2 or receiving chronic dialysis) or history of nephrectomy or kidney transplant (regardless of renal function).
6. Current severe heart failure (New York Heart Association [NYHA] class III or IV).
7. Poorly controlled hypertension despite lifestyle modifications and pharmacotherapy.
8. Any life-threatening condition with life expectancy <2 years, other than vascular disease, that might prevent the subject from completing the study.
9. Severe asthma that is poorly controlled on pharmacotherapy.
10. Positive pregnancy test (all female subjects of childbearing potential must have a urine or serum β-human chorionic gonadotropin pregnancy test performed within 7 days prior to randomization) or is known to be pregnant or lactating.
11. History of anaphylaxis, anaphylactoid (resembling anaphylaxis) reactions or severe allergic responses.
12. Alcohol or drug abuse within the past 6 months. Current mental condition (psychiatric disorder, senility or dementia), which may affect study compliance or prevent understanding of the aims, investigational procedures or possible consequences of the study.
13. Current or planned chronic administration of strong oral or injectable cytochrome P-450 isoenzyme 3A4 (CYP3A4) inhibitors.

14. Subjects with 2 known birth parents of at least 50% Japanese, Chinese, or Korean ancestry (or if unknown, a reasonable likelihood of such ancestry) must have a blood sample collected for assessment of Lp-PLA_2 activity by the central laboratory prior to randomization. Those with Lp-PLA_2 activity ≤20.0 nmol/min/mL will be excluded from participation in the study (online appendix).[4]
15. Previous exposure to darapladib (SB-480848).
16. Use of another investigational product within 30 days or 5 half-lives (whichever is the longer) preceding the first dose of darapladib or matching placebo.
17. Currently in a study of an investigational device.
18. Any other reason the investigator deems the subject to be unsuitable for the study.

[4] Subjects homozygous for the 279F variant have no circulating levels of Lp-PLA_2 and would not expect to benefit from Lp-PLA_2 lowering therapy. This allele is most common in those of Japanese, Chinese, and Korean ancestry.

eAppendix 3. Clinical End Point Definitions

3.1 Death

Death will be defined as all-cause mortality. Cause of death will be classified as either cardiovascular or non-cardiovascular. All deaths that are unwitnessed will be assumed to be cardiovascular in nature unless a non-cardiovascular cause can be clearly provided.

1) Cardiovascular

Cardiovascular death is defined as death due to documented cardiovascular cause. Causes of cardiovascular deaths include but are not limited to deaths resulting from stroke, arrhythmia, sudden death (witnessed or unwitnessed), myocardial infarction, heart failure, pulmonary embolism, peripheral arterial disease, or complications of a cardiovascular procedure. Additionally, death not clearly attributable to non-cardiovascular causes will be considered CV death.

a) Coronary heart disease (CHD) death is defined as fatal myocardial infarction, death caused by documented cardiac arrest (e.g., ventricular fibrillation or other lethal arrhythmia without known secondary causes), or death resulting from heart failure in a patient with known CHD, death from other forms of acute or chronic CHD, unwitnessed death of unknown origin or sudden death.

2) Non-cardiovascular

Non-cardiovascular deaths include deaths due to a clearly documented non-cardiovascular cause. Non-cardiovascular deaths will be further classified into the categories: hemorrhage, neoplasm/cancer, trauma, infection/sepsis, post non-cardiovascular surgery, pulmonary, suicide, and other causes of death (specify).

3.2 Myocardial Infarction

Myocardial infarction is defined as adapted according to the Universal Definition of MI.[1]

Myocardial Infarction: evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Under these conditions any one of the following criteria meets the diagnosis for myocardial infarction.

1) For a patient with no recent revascularization and in whom biomarkers are not elevated at baseline, detection of rise and/or fall of cardiac biomarkers (CK-MB or troponin) with at least one value above the 99th percentile of a normal reference population (URL = upper reference limit) *(Note: The MI decision limit or ULN can be used if 99th percentile is unavailable*).
In instances where both cardiac biomarkers (troponin and CK-MB) are available (drawn at similar time points) and are discordant, biomarker criteria will be applied using cardiac troponin. Biomarker changes must occur together with evidence of myocardial ischemia with *at least one* of the following:

i) Symptoms of ischemia lasting $\geq$10 minutes;

ii) ECG changes indicative of new ischemia (new ST-T changes or new left bundle branch block) as described below:

- **ST elevation**
  - New ST elevation at the J-point in two contiguous leads with the cut-off points:
    - ≥0.2 mV in men or ≥0.15 mV in women in leads V2–V3

    AND/OR

    - ≥0.1 mV in other leads
- **ST depression and T-wave changes**
  - New or presumed new horizontal or down-sloping ST depression ≥0.05 mV in two contiguous leads;

    AND/OR

  - New or presumed new T inversion ≥0.1 mV in two contiguous leads with prominent R-wave or R/S ratio >1

iii) Development of pathological Q waves in ECG

Any Q-wave in leads V2–V3 ≥0.02s OR QS complex in leads V2 and V3. Q-wave ≥0.03s and ≥0.1 mV deep OR QS complex in leads I, II, aVL, aVF, or V4–V6 in any two leads of a contiguous lead grouping (I, aVL,V6; V4–V6; II, III, and aVF). NOTE: The same criteria are used for supplemental leads V7–V9, and for the Cabrera frontal plane lead grouping: R-wave ≥0.04s in V1–V2 and R/S ≥1 with a concordant positive T-wave in the absence of a conduction defect.

iv) Imaging evidence of *new* loss of viable myocardium or *new* regional wall motion abnormality.

2) For a patient with no recent revascularization in whom biomarkers (troponin or CK-MB) from a recent MI remain elevated, the patient must meet the following criteria:

- Cardiac biomarker (CK-MB or troponin) re-elevation defined as:

  a) Documentation the biomarker was decreasing prior to the new suspected MI, **AND**

  b) Increase by at least 50% of the previous value,

In instances where both cardiac troponin and CK-MB are available (drawn at similar time points) and are discordant, biomarker criteria will be applied using cardiac troponin.

AND, at least one of the following:

i) Symptoms of ischemia lasting ≥10 minutes;

ii) ECG changes indicative of new ischemia (new ST-T changes or new left bundle branch block) as described previously above;

iii) Development of pathological Q waves in ECG, as described previously above;

iv) Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.

3) Sudden, unexpected cardiac death, involving cardiac arrest, often with symptoms suggestive of myocardial ischemia, and accompanied by presumably new ST elevation, or new left bundle branch block, and/or evidence of fresh thrombus by coronary angiography and/or autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood.

4) Within 24 hours after PCI a patient must have EITHER:

1) CK-MB ≥3× ULN and, if the pre-PCI CK-MB was >ULN, both an increase by at least 50% over the previous value and documentation that CK-MB was decreasing prior to the suspected recurrent MI;

OR

2) Pathologic findings of an acute MI. *Note: symptoms are not required.*

Note: If cardiac troponin measurements are the only cardiac biomarker data available, they may be used by the CEC, along with the ECG and clinical scenario, in the adjudication of suspected MI after the PCI

5) Within 72 hours after CABG a patient must have EITHER:

1) CK-MB ≥5× ULN and, if the pre-CABG CK-MB was >ULN, both an increase by at least 50% over the previous value and documentation that CK-MB was decreasing prior to the suspected recurrent MI;

AND

2) At least one of the following supportive criteria:

a) Development of new, abnormal Q waves, as described previously above. b)

Angiographically documented new graft or native coronary occlusion

c) Imaging evidence of new loss of viable myocardium d)

Documented new left bundle branch block (LBBB)

OR

3) Pathologic findings of an acute MI.

Note: symptoms are not required.

Note: If cardiac troponin measurements are the only cardiac biomarker data available, they may be used by the CEC, along with the ECG and clinical scenario, in the adjudication of suspected MI after the CABG surgery.

6) Pathological findings of an acute MI.

7) Myocardial infarction diagnosed post-randomization: Any one of the following criteria meets the diagnosis for a myocardial infarction which is noted post-randomization during the conduct of the trial (eg. Silent myocardial infarction discovered by electrocardiogram obtained at a routine visit when compared with electrocardiogram obtained at previous visit):

- Development of new pathological Q waves with or without symptoms as described below:
  - Any Q-wave in leads V2–V3 ≥0.02s **OR** QS complex in leads V2 and V3
  - Q-wave ≥0.03s and ≥0.1 mV deep OR QS complex in leads I, II, aVL, aVF, or V4–V6 in any two leads of a contiguous lead grouping (I, aVL,V6; V4–V6; II, III, and aVF). NOTE: The same criteria are used for supplemental leads V7–V9, and for the Cabrera frontal plane lead grouping:
  - R-wave ≥0.04s in V1–V2 and R/S ≥1 with a concordant positive T-wave in the absence of a conduction defect
- Imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause and can be demonstrated to have occurred post-randomization.
- Pathological findings of a healed or healing myocardial infarction that is believed to have occurred post-randomization.

Additional sub classification of MI by etiology

According to new Joint ESC/ACCF/AHA/WHF Task Force recommendations for the Redefinition of Myocardial Infarction[1] the following classifications for the type of MI will be further used. Events will only be sub classified into the following categories if they first meet the primary definition of myocardial infarction as defined above.

Clinical classification of different types of myocardial infarction

MI type	Description	Note
Type 1	Spontaneous myocardial infarction related to ischemia due to a primary coronary event such as a plaque erosion and/or rupture, fissuring, or dissection	Events classified as Type 1 should not meet criteria for other types below. Specifically, stent thrombosis should not be categorized as Type 1. Any non-periprocedural MI, that does not clearly have a secondary cause (Type 2), should be classified as Type 1
Type 2	Myocardial infarction secondary to ischemia due to either increased oxygen demand or decreased supply, e.g. coronary artery spasm, coronary embolism, anemia, arrhythmias, hypertension, or hypotension.	Event is presumed to be non-thrombotic in etiology
Type 3	Sudden unexpected cardiac death, including cardiac arrest, often with symptoms suggestive of myocardial ischemia, accompanied by presumably new ST elevation, or new LBBB, or evidence of fresh thrombus in a coronary artery by angiography and/or at autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood.	Type 3, will be rare, these are cases where the subject died before biomarkers were obtained but had clear ECG or angiographic evidence of an acute MI
Type 4a	Myocardial infarction associated with PCI	As defined under the primary definition of MI as stated above
Type 4b	Myocardial infarction associated with stent thrombosis as documented by angiography or at autopsy	See definition of stent thrombosis below (ARC definite)
Type 5	Myocardial infarction associated with CABG	As defined under the primary definition of MI as stated above

3.3 Stroke

Stroke is defined as the presence of **a new focal neurologic deficit thought to be of vascular origin, with signs or symptoms lasting >24 hours, or results in death (in <24 hours).** It is strongly recommended that neuroimaging, such as computed tomography (CT) scan or magnetic resonance imaging (MRI) is performed to confirm diagnosis. In the absence of neuroimaging, additional functional deficit must be documented by a change in the modified Rankin Score.

If neurologic symptoms last <24 hours, new brain infarction has to be confirmed by diffusion weighted MRI showing the presence of a new brain infarct. Alternate forms of neuroimaging will be accepted only if it can be demonstrated that a defect is new. In addition, location of a defect must be consistent with the observed neurological symptoms. Confirmed retinal arterial ischemic event (embolism, infarction) will be considered a stroke. Subarachnoid, epidural and subdural hemorrhage will not be considered a stroke under the endpoint definition.

Stroke will be further classified as ischemic, hemorrhagic (intraparenchymal), ischemic stroke with hemorrhagic conversion or type uncertain, see below:

- *Hemorrhagic:* A stroke with documentation of intracranial hemorrhage on imaging (eg, computed tomography (CT) scan or magnetic resonance imaging (MRI) scan) in the cerebral parenchyma. Subarachnoid, epidural and subdural hemorrhage will not be considered a stroke under the endpoint definition. Microhemorrhages incidentally discovered on brain imaging without associated symptoms will not be considered a stroke event.

- *Ischemic:* A stroke that results from a thrombus or embolus impairing central nervous system perfusion.

- *Cerebral infarction with blood felt to represent hemorrhagic conversion and not a primary hemorrhage.* Hemorrhagic conversion usually occurs on the cortical surface. Hemorrhagic conversion in the deeper brain requires evidence of non-hemorrhagic infarction in the same vascular territory. Microhemorrhages evident on brain imaging in the cortex or deep brain structures, are not considered to be consistent with a hemorrhagic conversion endpoint.

- *Uncertain/No imaging performed:* if the type of stroke could not be determined by imaging or other means (from lumbar puncture, neurosurgery, or autopsy).

3.4 Urgent coronary revascularization for Myocardial Ischemia

Urgent coronary revascularization for myocardial ischemia is defined as ischemic discomfort *≥10 minutes* at rest that prompts coronary revascularization (PCI or CABG) during the same hospitalization or resulting in hospital transfer for the purpose of coronary revascularization. PCI is defined as any attempt at revascularization even if not successful (e.g., angioplasty, atherectomy or stenting).

Potential ischemic events meeting the criteria for myocardial infarction will not be adjudicated as urgent coronary revascularization for myocardial ischemia.

Ischemic discomfort is defined as chest pain or discomfort or equivalent (eg neck or jaw symptoms, dyspnea believed to represent an angina pectoris equivalent) believed due to impaired coronary flow secondary to atherosclerotic disease.

3.5 Hospitalization for Unstable Angina

Hospitalization for unstable angina is defined as one of the following but **not fulfilling the criteria for MI**:

a) Ischemic discomfort at rest ≥*10 minutes* associated with ECG changes (as described below) leading to hospitalization OR

b) Ischemic discomfort at rest ≥*10 minutes* regardless of ECG changes leading to hospitalization AND coronary revascularization (or attempted revascularization) during the same admission OR

c) Ischemic discomfort at rest ≥*10 minutes* in hospital associated with ECG changes (as described below) OR

d) Ischemic discomfort at rest ≥*10 minutes* in hospital without ECG changes resulting in coronary revascularization (or attempted revascularization) during the same admission.

Ischemic discomfort is defined as chest pain or discomfort or equivalent (eg neck or jaw symptoms, dyspnoea believed to represent an angina pectoris equivalent) believed due to impaired coronary flow secondary to atherosclerotic disease.

ECG changes are defined as: New or presumed new ischaemic ECG changes (transient ST elevation ≥1 mm (0.1 mV) or ST depression ≥0.5 mm (0.05 mV), or T wave inversion ≥1 mm (0.1 mV) in at least 2 contiguous leads).

The event will not be considered unstable angina if, after invasive/non-invasive testing or other diagnostic testing, the discomfort is found not to be caused by myocardial ischemia.

3.6 Hospitalization for Heart Failure

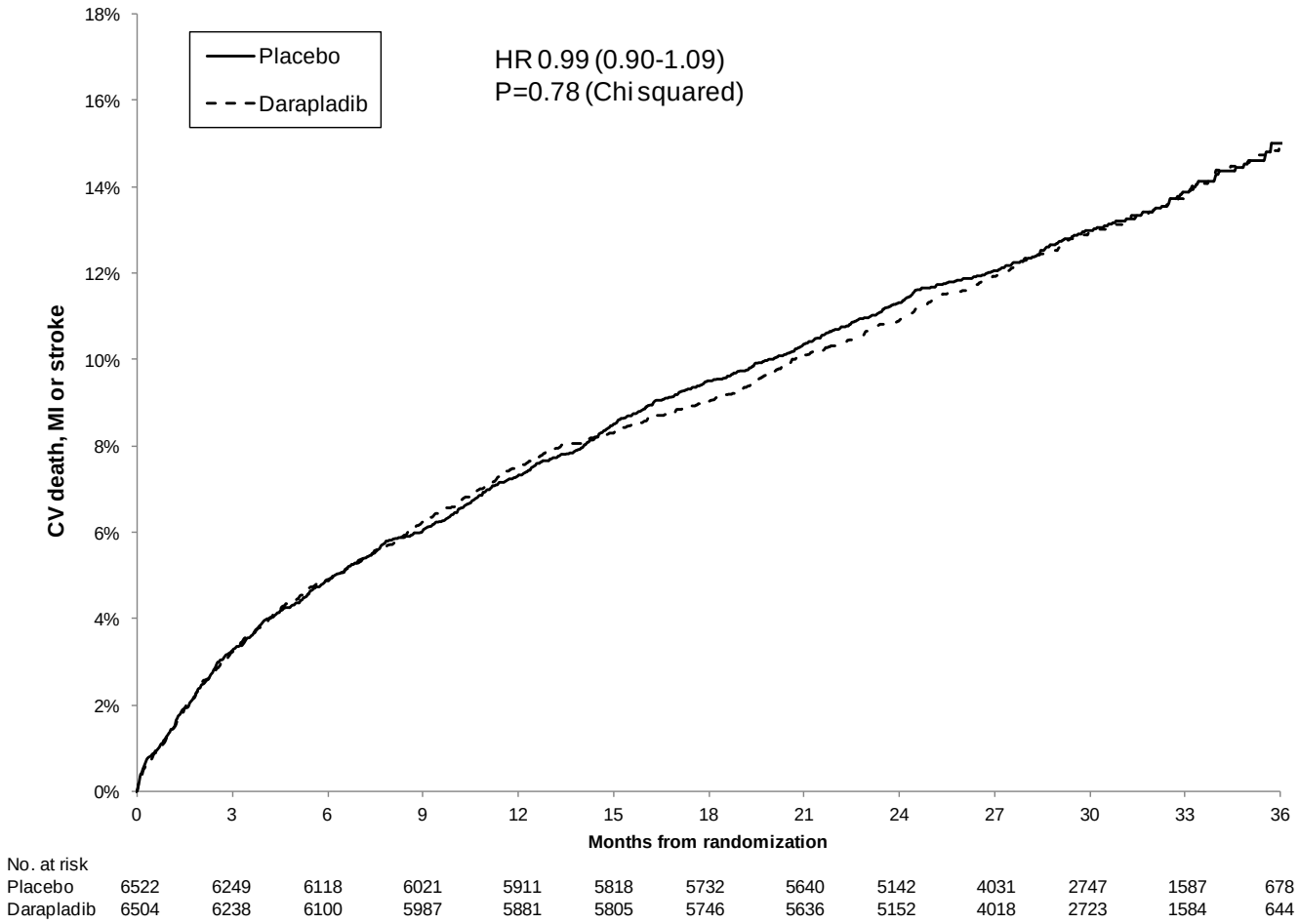
Heart failure requiring hospitalization is defined as admission to hospital or attendance at an acute health care facility for administration of intravenous diuretic treatment, escalation of diuretic doses, and/or inotropes. Confirmation of heart failure diagnosis is required by chest imaging demonstrating pulmonary congestion or edema, OR, in patients *without* available chest imaging, at least one of the following: Pulmonary edema, (i.e. rales >1/3 up the lung fields thought to be of cardiac causes), pulmonary capillary wedge pressure >18 mmHg or BNP >500 pg/ml (or NT-terminal prohormone BNP >2500 pg/ml).

3. Lp-PLA$_2$ Activity Assay Methodology

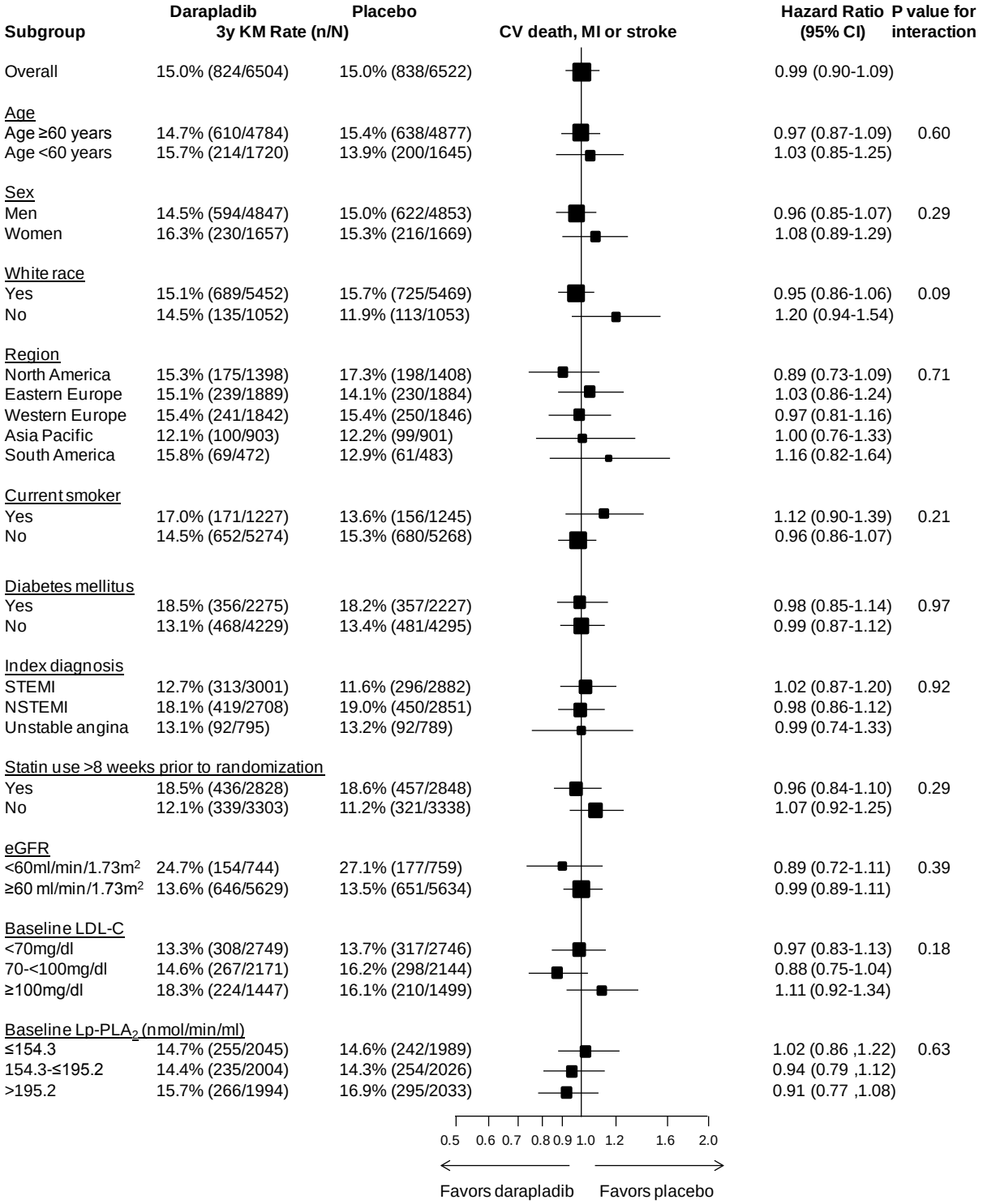
As part of the study protocol, a sample of venous blood was obtained in EDTA-treated tubes from the subjects at the time of enrollment for assessment of Lp-PLA$_2$ activity. The plasma component was frozen and shipped to a central laboratory where samples were stored at -70^{o}C or colder. Lp-PLA$_2$ activity was measured using the PLAC™ test for LpPLA$_2$ activity at diaDexus (South San Francisco, CA, USA). The assay uses [^{3}H]-platelet activating factor (PAF) as the reaction substrate and enzyme activity is expressed as nanomoles of PAF hydrolyzed per minute per mL plasma samples (nmol/min/mL). The measuring range of the assay is 10 to 400 nmol/min/mL with the low end of the range based on the limit of quantitation (LOQ). Intra-assay and inter-assay variability were determined by testing four human serum samples and two controls with Lp-PLA$_2$ activities ranging from 95 to 345 nmol/min/mL. Total precision coefficients of variation were <3%.

4. Supplemental Figures and Tables

eFigure 1. Cumulative incidence curves for the secondary endpoint CV death, MI or stroke



eFigure 2. Subgroups of interest for the secondary composite endpoint of CV death, MI or stroke.



eTable. Summary of MI according to the Universal Classification of MI by randomized treatment arm[1]

Types of MI	**Placebo (n=6504)**	**Darapladib (n=6522)**
Type 1: Spontaneous MI	443	426
Type 2: MI secondary to oxygen supply:demand imbalance	83	56
Type 3: Sudden unexpected cardiac death	9	3
Type 4a: MI associated with PCI	10	16
Type 4b: MI associated with stent thrombosis	57	71
Type 5: MI associated with CABG surgery	0	2

Abbreviations: MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft

5. eReferences

1. Thygesen K, Alpert JS, White HD, on behalf of the Joint ESC-ACC-AHA-WHF Task Force for the Redefinition of Myocardial Infarction. *European heart journal* 2007;28:2525-38.
2. Cutlip DE, Windecker S, Mehran R, et al. Clinical end points in coronary stent trials: a case for standardized definitions. *Circulation* 2007;115:2344-51.