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Pivotal National Trial Uses Newest Interventional Radiology Treatment to Bust Blood Clots in Legs

New Treatment May Revolutionize Care for Patients With Deep Vein Thrombosis; \$10 Million National Institutes of Health ATTRACT Study To Determine if Drug-Device Technique Can Prevent Post-Thrombotic Syndrome

FAIRFAX, Va.—ATTRACT—the first major national trial of a catheter-based treatment for deep vein thrombosis—will evaluate the use of clot-dissolving drugs in combination with clot removal devices to prevent post-thrombotic syndrome in patients with DVT (the formation of a blood clot in a leg vein). PTS, a common irreversible complication of DVT, causes permanent damage to the veins, resulting in debilitating chronic leg pain, swelling, fatigue and/or skin ulcers. About 25–50 percent of DVT patients develop PTS when treated with blood thinners alone. While early treatment with blood thinners is important to prevent a life-threatening pulmonary embolism, blood thinners alone do not dissolve the existing clot, which remains in the leg. Preliminary studies have shown that interventional clot-busting treatments can—unlike standard DVT therapy—remove clots and have strong potential to prevent PTS. The outcomes of this pivotal multicenter trial—to be funded at more than \$10 million by the National Institutes of Health's National Heart, Lung and Blood Institute (NHLBI)—are likely to change the way DVT is treated in the United States.

"The ATTRACT trial could fundamentally shift the 50-year-old DVT treatment paradigm to one that includes interventional clot removal as an essential element of standard DVT care," said interventional radiologist Suresh Vedantham, M.D., who will lead the trial. "By funding this study, the NHLBI has clearly recognized the strong potential of interventional radiology clot removal treatments for DVT to improve public health," added the associate professor at the Washington University School of Medicine's Mallinckrodt Institute of Radiology in St. Louis, Mo.

ATTRACT (Acute Venous Thrombosis: Thrombus Removal With Adjunctive Catheter-Directed Thrombolysis) is a multicenter, randomized trial "that will definitively determine if the newest clot-busting treatment (pharmacomechanical catheter-directed thrombolysis or PCDT) prevents post-thrombotic syndrome in patients with DVT," said Vedantham. PCDT combines the use of a clot-dissolving drug with a catheter-mounted miniature clot removal device, allowing an interventional radiologist to break up the clot and remove it from the vein, restoring blood flow. "PTS is a serious complication of DVT that is under recognized and potentially preventable if we are able to dissolve the clots early, before permanent damage to the vein occurs," he noted. "Established PTS is a lifelong, irreversible condition for which there are no consistently effective treatments. Its prevention is extremely important; however, physicians have historically neglected the prevention of PTS," said Vedantham. "The groundbreaking combination of clot-busting drugs with innovative device technology—pioneered by interventional radiologists—now enables clot removal in a safer and more efficient manner, often in a single procedure session. These advances will greatly increase the use of interventional DVT treatments," added Vedantham.

"This research is critical. The Society of Interventional Radiology Foundation initiated a DVT research consensus panel four years ago, bringing together clinicians and scientists from all disciplines and from all settings—academia, private practice, government and industry—and determining the need for the ATTRACT trial," said Michael Darcy, M.D., chair of the board of directors for SIR Foundation, a scientific foundation dedicated to fostering research and education in interventional radiology. The SIR Foundation has been a critical partner in developing the ATTRACT trial, helping to coordinate the site selection process and partnering with the ATTRACT research team to conduct the trial, said Vedantham.

DVT is the formation of a blood clot, known as a thrombus, in a deep leg vein. This can be a very serious condition that often causes permanent damage to the leg, known as post-thrombotic syndrome. Early treatment with

blood thinners is important to prevent a life-threatening pulmonary embolism, but blood thinners do not dissolve the existing clot, which remains in the leg. While many patients' clots will slowly dissolve over time, often the vein wall and vein valves become irreversibly damaged in the process. "PTS develops as a direct result of having the blood clot stay in the vein. The blood clot continues to block the vein and permanently damages its one-way valves, resulting in the pooling of blood in the leg, chronic leg pain, swelling and fatigue and sometimes skin ulcers. It's logical that immediate clot removal will prevent PTS," said Vedantham.

The ATTRACT trial—the first NIH-funded multicenter, randomized trial of any interventional DVT therapy will begin later this year. The trial will assess the presence and severity of PTS, quality of life, relief of pain and swelling, safety and costs. At least 28 U.S. clinical centers will enroll 692 patients and monitor their health for two years, said Vedantham, who is chair of the DVT Research Committee of SIR's Venous Forum and vice chair of the Venous Disease Coalition. The Society of Interventional Radiology is a member of the Venous Disease Coalition.

Please note: Suresh Vedantham, M.D., is scheduled to address "Will Clot-Busting Therapies Revolutionize VTE Care?" from 11 a.m.-12:30 p.m. (Eastern) on Monday, Sept. 15, during the annual meeting of the Venous Disease Coalition, which will be held at the Grand Hyatt Hotel, 1000 H St. NW, Washington, D.C. He is also scheduled to speak on "How Do We Best Educate Health Care Professionals About Venous Disease?" from 2-2:30 p.m. (Eastern).

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About the Society of Interventional Radiology Foundation

SIR Foundation is a scientific foundation dedicated to fostering research and education in interventional radiology for the purposes of advancing scientific knowledge, increasing the number of skilled investigators in interventional radiology and developing innovative therapies that lead to improved patient care and quality of life.

Interventional radiologists are vascular experts who invented angioplasty and the catheter-delivered stent, which were first used in the legs to treat peripheral arterial disease. They provide vascular disease management and specialize in minimally invasive treatments. Visit <u>www.SIRfoundation.org</u>.

Local interviews, medical illustrations and broadcast-quality video footage are available by contacting SIR's communications department via e-mail at <u>mverrillo@SIRweb.org</u> or by phone at (703) 460-5572.