News Release

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NaviGate Cardiac Structures Inc. ("NCSI") reports world's first successful transcatheter implantation of 52-mm tricuspid valve into a transplanted-heart patient to correct "torrential" tricuspid regurgitation (TR)

LAKE FOREST, Calif., Aug. 30, 2017 — **NaviGate Cardiac Structures Inc. ("NCSI")** announced today that its GATE™ catheter-guided tricuspid atrioventricular valved stent (AVS) was implanted through the jugular vein six weeks ago into a patient's transplanted heart that was failing due to severe tricuspid valve insufficiency. The successful implantation of the GATE™ AVS at the Policlinico of the University of Padua, Italy, represents the first European patient treated with the NCSI tricuspid replacement heart valve. Three hours after the intervention the patient was awake and showing improved renal function. Now, approximately two months post-procedure, the patient continues to demonstrate clinical improvement and excellent valvular function. This brings the total number of NCSI GATE™ tricuspid implants without 30-day mortality to three.

The patient, a 67-year-old male with a long history of cardiac conditions received a heart transplant in 1990 for post-ischemic dilated cardiomyopathy and had a host of comorbidities [hypertension, osteoporosis with vertebral fracture, radical prostate surgery due to cancer (2006) and upper and middle right lobectomy for bullous dysplasia (2009)]. Since the beginning of 2017 the patient has had five hospitalizations for heart failure due to severe regurgitation of the tricuspid valve of his transplanted heart. The patient was released home (five days after the procedure), the GATE™ showed a transvalvular gradient of 2 mmHg with a trivial perivalvular leak. Also notable was that at discharge the patient's renal function had improved significantly and a dramatic reduction in diuretics was prescribed.

"This is the first size-52 mm GATE™ tricuspid AVS implanted, and the first tricuspid valve replacement in a failing transplanted heart in one of the leading cardiac centers in Europe. Our team is working diligently to reach the initiation of clinical trials in various centers in Europe from where we have received requests for our tricuspid replacement valve," said **Dr. Rodolfo Quijano,** President and CEO of NCSI

NCSI differentiates the GATE™ from all other valves presently manufactured for atrioventricular heart valve replacement by its unique delivery design in the form of a diffuser or truncated cone. This design for all annulus-capturing sizes exhibits a low-height profile that can be more easily threaded through the vasculature to reach the atrioventricular valves, allowing it to reside without protruding into either of the adjacent chambers (atrium or ventricle) of dilated mitral or tricuspid valves, as protrusion is known to cause certain complications.

Tricuspid Regurgitation (TR) has lately received intensive attention after being ignored for decades as the aortic and mitral valves have been the focus of efforts in new technology for repair or replacement. Moderate-to-severe TR is a burgeoning health problem both in the developed and underdeveloped world, and estimates in the US alone are approaching the two million patient mark yearly. When at the severe stage, patients are at prohibitive risk for standard cardiac surgery. The GATE™ represents a new approach in the search for a safer and more effective treatment of this dreaded condition.

Background

The heart has two kinds of valves: *atrioventricular* and *semilunar* valves. The atrioventricular heart valves are the mitral and tricuspid valves, which separate the atriums of the heart from the ventricles. NCSI questioned if the atrioventricular GATE™ valve would be suitable for a transplanted heart and consulted with its Scientific Advisory Board, a group that comprises, among others, Dr. Rebecca Hahn from Columbia University Medical Center, N.Y., an expert cardiologist-echocardiographer in atrioventricular valves; and Dr. Azeem Latib a well-known interventional cardiologist with extensive expertise in treatment of tricuspid valve disease from San Rafaelle Medical Center in Milan, Italy.

The NCSI SAB, acting as an *ad hoc* patient selection committee, examined the case and determined that the GATE™ device would be suitable for the transplanted heart. The patient had become symptomatic for right heart failure and was considered at prohibitive risk for standard cardiac surgery and opted to make a compassionate plea to Drs. Andrea Colli and Dr. Gino Gerosa, his physician surgeons, for the NCSI valved stent under development. The Italian Ministry of Health allowed the implant as a last resort for the patient. Prof. Giusseppe Tarantini, Chief of Interventional Cardiology, and Dr. Colli proceeded with the implantation. It was ascertained that the measured diameter of the dilated annulus of the incompetent valve was so large that it would require a 52mm GATE™, the largest tricuspid valved stent, in order to correct the torrential TR. After receiving the valve, the patient became stable and three hours after was awake and showing improved renal function.

Prof. Tarantini found the GATE™ device to be very "user friendly," adding: "I like this valve, it is easy to use and took less than 10 minutes to place once we entered the right atrium. This will be helpful to many patients with advanced tricuspid insufficiency." Prof. Tarantini will be leading the transjugular clinical implants in Padua while Prof. Gerosa and Colli will lead the transatrial surgical implants as the clinical trials commence.

About GATE™

- Most valved stents are cylindrical with a small radius near 30mm making them unable to capture and hold the dilated annulus typical of functional tricuspid or mitral regurgitation.
- NCSI's GATE valved stent features a large distal diameter to capture the dilated annulus, which is useful to minimize the height of the valve thereby reducing potential intrusion into the heart chambers.
- GATE's conical shape also serves to diffuse the pressure across the valve and reduce resistance to flow caused by cylindrical stents, i.e. better flow.

About NCSI

NaviGate Cardiac Structures Inc. (www.navigatecsi.com) is an early-stage company focused on developing transcatheter solutions for the less-invasive treatment of atrioventricular valve regurgitation. The NaviGate valved-base technology was licensed from Cleveland Clinic and further modified and developed by NCSI.

CAUTION: NCSI's technology is not approved for investigational use in the United States.

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