Journal of Neurointerventional Surgery; JNIS BMJ Journal. Oral Abstract 20th SNIS annual Meeting August 2, 2023 San Diego California, USA

Oral Abstract Title: Novel Saccular Endovascular Aneurysm Lattice (SEAL Device) PRE-SEAL IT Early Clinical Feasibility TRIAL: Procedural, 24-hours, and 3-Month Safety and Effectiveness Independent Core Lab Adjudicated Outcomes

Boris Pabón, MD[1]; Victor Torres, MD[1]; Syed F Zaidi, MD[2], Hisham Salahuddin, MD[3]; Manuel Patiño, MD[1]; Felipe Peláez, MD[1]; Jorge Mútis, MD[1]; Margarita Cardozo, MD[1]; Ammad Hussain, MD[4]; Irfan Lutfi, MD[5]; Mouhammad Ali, MD[6]; Saima Ahmed, MD[7]; Edgard Pereira, MD[8]; Aamir Badruddin, MD[8]; Keith Woodward, MD[9]; Thomas Wolfe, MD[8]; Claire Langerford, PhD[10]; Brian Jankowitz, MD[11]; Vincent Costalat, MD[12]; David Altschul, MD[13]; Mehrnoosh Kaffashi, MD, MPH[10]; Osama O. Zaidat, MD, MS[8].

[1]Universidad De Antioquia, Medellin, COLOMBIA
[2]University of Toledo, Toledo, OH
[3]Antelope Valley Medical Center, Thousand Oaks, CA
[4]Zia Medical Center L.L.C, Dubai, UNITED ARAB EMIRATES
[5]Civil Hospital Karachi, Karachi, PAKISTAN
[6]Dr. Ziauddin Hospital, Karachi, PAKISTAN
[7]Lahore General Hospital, Lahore, PAKISTAN
[8]Galaxy Therapeutics, Inc, Milpitas, CA
[9]Vista Radiology, Knoxville, TN
[10]MedX CRO, LLC, Toledo, OH
[11]Penn Medicine, Philadelphia, PA
[12]CHU de Montpellier, Montpellier, FRANCE
[13]Montefiore Medical Center, Bronx, NY

Introduction: The first-in-human PRE-SEAL IT trial was designed to assess the feasibility, safety, and effectiveness of the novel Saccular Endovascular Aneurysm Lattice (SEAL™) system in patients with previously untreated ruptured and unruptured wide-neck intracranial aneurysms (IA). Here, we present the final demographic, procedural, 24-hour, and 3-month safety and effectiveness results from the 33 aneurysm that were treated in 29 patients with the SEAL™ device and enrolled in the PRE-SEAL IT study.

Methods: PRE-SEAL IT is a prospective, interventional, core-lab adjudicated, single-arm study performed in Medellin, Columbia and Pakistan. From January 2022 through March 2023, 29 patients with 33 IAs were enrolled into the PRE-SEAL IT trial and follow-up is ongoing. Key inclusion criteria included: 1. Age 20-80 years, 2. Saccular shape, bifurcation, or terminus IA, 3.Wide neck aneurysm with neck size ≥4mm or dome-to-neck ratio <2, and 4. IA diameter 2mm to 25mm. Consented and enrolled patients were treated with the SEAL™ device. A follow-up DSA was performed at 24-hours, 6 months, and 12 months and a MRA at 3 months. Angiographic occlusion (Roy Raymond (RR) and Web Occlusion Scale (WOS)) was adjudicated by an independent interventional neuroradiologist (Oculus Imaging, TN, USA). Here we Present the 3-month safety and effectiveness outcomes.

Results: 33 aneurysms in 29 patients (twenty-two women and 7 men) were treated with the SEAL™ device, with a mean age of 61.0± 13.5 years. Of the 33 IA, the majority were anterior circulation (81.8%),

bifurcation (75.8%), and unruptured (87.9%). Mean aneurysm width was 6.1 ± 3.0mm, with a mean neck size of 4.2±1.7mm and mean neck to dome ratio of 1.4±0.4. The SEAL Arc was used in 48.5% and SEAL Base in 51.5% of cases. No technical complications were observed in the study and technical success was achieved in 100% of cases. Immediate post-procedure complete occlusion (Grade A, B) was achieved in 4 patients (12.1%) and adequate occlusion (Grade A, B, C) in 8 (24.2.%). At 24-hour follow-up, 12 patients (36.4% or 1/3 of patients) had complete occlusion, and 19 patients (57.6%) achieved adequate occlusion. At 3 months 20/27 (74.1%) (RR I and WOS A), achieved complete occlusion, and 22/27 (81.5%) achieved adequate occlusion (RR I and II). No cases of peri-procedural stroke or new subarachnoid hemorrhage were reported up to the 3 months follow up.

Conclusion: The final procedural, 24-hour, and 3-month, follow-up results of the PRE-SEAL-IT trial demonstrated promising occlusion rates at post-procedural, 24-hour, and 3 months follow-up with no safety concerns.