Simplify Medical Completes Enrollment in U.S. IDE Pivotal Trial of Simplify® Disc for Two-Level Cervical Disc Replacement

Sunnyvale, CA – November 14, 2018 – Simplify Medical Pty Ltd., maker of the Simplify® cervical artificial disc, today announced that it has completed the enrollment and treatment of all patients in its U.S. Investigational Device Exemption (IDE) pivotal trial evaluating the Simplify® Disc for two-level cervical disc replacement. The Simplify Disc is designed for biomechanical motion, anatomical height-matching, and MRI compatibility with a goal of simplifying the treatment of degenerative disc disease.

The prospective, multi-center clinical trial enrolled a total of 200 patients at 18 clinical sites across the United States. The primary endpoint of the study is the clinical success rate of Simplify Disc in two contiguous levels from C3 to C7 compared with two-level anterior cervical discectomy and fusion (ACDF). The Company announced the completion of enrollment for its one-level IDE trial in February 2018.

David Hovda, CEO of Simplify Medical, said, "Our two-level trial has generated an exceptional level of interest, which has allowed us to complete study enrollment more quickly than anticipated. We thank all of our dedicated surgeon investigators who have participated in the trial and look forward to working with them to complete the study."

Domagoj Coric, MD, Chief of Neurosurgery at Carolinas Medical Center and national co-primary investigator for the study as well as co-primary investigator of the one-level study, stated, "Given its compelling feature set and the early positive feedback, I believe the Simplify Disc represents the future of cervical disc arthroplasty. I look forward to providing my patients with this technology as it becomes commercially available and am eager to share clinical data when available."

Richard Guyer, MD, chairman of the Texas Back Research Institute Foundation and national co-primary investigator for the study as well as co-primary investigator of the one-level study, commented, "The Simplify Disc has the potential to offer an attractive alternative for two-level disease by simplifying procedure complexity compared to other marketed devices, providing motion, and better matching patient anatomy with lower disc heights that avoid excessive wear. We look forward to sharing outcomes at upcoming spine meetings."

The Simplify Disc is being evaluated in separate IDE trials in the U.S. for one- and two-levels. The Simplify Disc is CE Marked in Europe and commercially available in select European markets. Internationally, early market feedback has shown substantial improvement in patient pain scores and functional improvement after treatment.

About Simplify® Disc

Simplify® Disc is a motion-preserving cervical artificial disc designed to allow for advanced imaging capability of MRI, and to better match patients' anatomies. It is composed of advanced, primarily non-metal materials (PEEK-on-ceramic) to permit the full diagnostic imaging capability of MRI and may eliminate the need for CT/Myelogram and CT imaging in order to minimize patient exposure to radiation. The Simplify Disc is anatomically designed, offering a broader range of disc heights including low height

implant options to better fit patients' anatomies. With no metal in its articulating components, the disc is also designed for low levels of wear to optimize long-term durability. Implantation of the Simplify Disc is accomplished in a straightforward, three-step procedure.

About Simplify Medical
Simplify Medical is a medical device company focused on cervical spinal disc arthroplasty, using innovative, MRI-compatible materials designed to decrease the need for ionizing radiation and enhance patient options. Simplify Medical is located in Sunnyvale, California. To learn more, visit http://www.simplifymedical.com/.

CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use.

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