Cerus Endovascular Receives FDA Breakthrough Device Designation for its Contour Neurovascular System™

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Cerus Endovascular Ltd. →
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FREMONT, Calif. and OXFORD, United Kingdom, Feb. 11, 2021 /PRNewswire/ -- Cerus Endovascular Ltd., a privately-held, commercial-stage medical device company, today announced that it has received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) for its Contour Neurovascular System™.

Breakthrough Device Designation is granted to medical devices and device-led combination products that provide the potential for a more effective treatment option for life-threatening or irreversibly debilitating diseases. The designation expedites the traditional development, assessment and review process, and enables medical professionals to get access to new developments quickly.

Indicated for the treatment of intracranial aneurysms, the Contour Neurovascular System™, composed of fine mesh braid, represents a unique intrasaccular advancement in the market, as it targets the neck of the aneurysm, away from the vulnerable dome. Additionally, the System is designed to be self-anchored for stability, re-sheathable for precise placement, and because it is deployed across the neck, sizing criteria are less restrictive than other commercially available intrasaccular devices, making it easier to use in the clinical setting.

"Today's news marks another significant milestone in our company's evolution and is the direct result of the commitment and strength of our scientific team, led by Dr. Lori Adels, Chief Compliance Officer," stated Dr. Stephen Griffin, President of Cerus Endovascular. "We

anticipate initiating our U.S. clinical trial, under an Investigational Device Exemption, soon and will work aggressively to bring our already CE Mark-approved Contour technology to the U.S. market."

"We look forward to working with U.S. regulatory authorities to expedite the availability of this innovative device that could provide an effective, minimally invasive treatment for bifurcated, intracranial aneurysms, a life threatening condition," noted Dr. Adels. "Under this program, the FDA will provide us with timely, interactive communication, priority review and FDA senior management engagement regarding the development of efficient and flexible clinical trial protocols, through to commercialization strategy and decisions."

Dr. Sam Milstein, Cerus' Chairman, added, "International sales of the Contour System continue to accelerate, as the medical communities abroad recognize the tangible benefits of this device. We look forward to having a similar impact in the U.S. market."

About Cerus Endovascular

Cerus Endovascular is a privately held, commercial-stage, medical device company engaged in the design and development of highly differentiated and proprietary interventional neuroradiology devices and delivery systems for the treatment of acute, life-threatening neurological conditions, specifically, intracranial aneurysms. The Company's CE Marked products, the Contour Neurovascular System™ and the Neqstent Coil Assisted Flow Diverter, expand the number and types of treatable intracranial aneurysms. For more information, please go to: www.cerusendo.com.

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