Cerus Endovascular Announces IDE Approval from the U.S. FDA to Conduct Clinical Study of the Contour Neurovascular System™

Patient Enrollment to Begin Within Three Months

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Cerus Endovascular Ltd. →
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FREMONT, Calif. and OXFORD, United Kingdom, April 21, 2021 /PRNewswire/ -- Cerus Endovascular Ltd., a privately held, commercial-stage medical device company, today announced that the U.S. Food and Drug Administration (FDA) has approved its Investigational Device Exemption (IDE) application to conduct a U.S. trial for the Contour Neurovascular System™, indicated for the treatment of intracranial aneurysms. The IDE approval follows the receipt of Breakthrough Device Designation from the FDA in February 2021.

"We are eager to move ahead with this important trial and anticipate patient enrollment beginning within the next three months," stated Dr. Stephen Griffin, President of Cerus Endovascular. "The IDE study protocol closely aligns with protocols of other intra-saccular aneurysm repair devices that have received FDA approval. Given the real-world patient outcomes we have experienced in Europe, where the Contour Neurovascular System™ has had CE mark approval since March 2020, we are hopeful that we will see similar, strong results from this trial."

The study, is designed to develop a robust data set to support the safety and efficacy of the Contour Neurovascular System™ for the endovascular embolization of wide-necked, bifurcated, saccular intracranial aneurysms. Study results will be submitted in a Premarket Approval (PMA) application to the FDA.

Dr. Sam Milstein, Cerus' Chairman, noted, "International demand for the System has been strong. Since obtaining CE Mark last year, we have completed cases in 121 new partner institutions within 12 countries across Europe and Asia. During this time, we have accumulated substantial additional clinical data as well as 12-month post-operative follow-up, all of which indicates that the Contour Neurovascular System™ is well positioned to meet the requisite endpoints of the U.S. study."

Dr. Lori Adels, Chief Compliance Officer of Cerus Endovascular, added, "Seven of the leading interventional neurovascular sites in the U.S. have already agreed to be active contributors to this study, a testament to the importance of this innovative device."

About the Contour Neurovascular System™

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. 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.

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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