DAWN™ Trial Results Demonstrate a 73% Reduction in Disability in Stroke Patients Treated up to 24 Hours

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Kalamazoo, Michigan (PRWEB) May 16, 2017 -- Results from the DAWN Trial were presented today at the European Stroke Organisation Conference (ESOC), providing compelling evidence that more patients suffering ischemic stroke may benefit from endovascular treatment. While previous randomized clinical trials have proven the benefit of stent retrievers within six hours of stroke onset, the DAWN Trial is the first to evaluate the late-window and wake-up stroke patient population.

The results from 206 patients enrolled in the trial demonstrated treatment with the Trevo® Retriever significantly decreased post-stroke disability and improved functional independence at 90 days when compared to medical management alone (48.6% vs 13.1%, probability of superiority >0.9999), a relative reduction in disability of 73% percent. The study showed that one in 2.8 patients treated with the Trevo Retriever within 24 hours of a stroke is saved from severe disability.* Treatment of these selected patients with thrombectomy appears to be as beneficial and imperative as in patients treated in the previously studied less-than-six-hour time window.

“This is great news for patients who present in the late time window who may still benefit from this treatment,” said co-principal investigator Dr. Tudor Jovin, from the University of Pittsburgh Medical Center. “The number needed to treat was only 2.8, indicating we may see a 270% increase in patients who are able to live an independent lifestyle free of severe disability.”

According to Dr. Raul Nogueira, co-principal investigator from Grady Memorial Hospital/Emory University, “Despite the longer times to treatment, the reduction in disability in this trial was highly significant – possibly representing the largest treatment effect ever seen in an endovascular stroke trial.† These results offer hope for thousands of stroke patients worldwide who arrive at the hospital outside the six hour treatment window.”

Stryker and the DAWN investigators believe the final results from the trial may lead to a critical shift in how physicians approach patient selection for endovascular therapy for stroke. The treatment effect shown in the DAWN Trial is compelling and a considerable development beyond what was previously demonstrated in the landmark stent retriever trials from 2015, which studied patients treated within six hours of stroke onset.

While the trial demonstrates that late and unwitnessed stroke populations may gain significant benefit from treatment with Trevo, it also shows that time is still a significant factor, and every minute of delay in care directly impacts functional independence following a stroke.

The Stryker-sponsored DAWN Trial was a randomized, controlled trial designed to evaluate functional outcomes at 90 days in stroke patients treated with mechanical thrombectomy using the Trevo Retriever compared to those receiving medical therapy alone. Patients were screened for inclusion in the trial if they had a stroke that started within six to 24 hours, or a stroke with an unknown time of onset: a significantly longer treatment window than the currently cleared thrombectomy indication.

“Stryker continues to push clinical advancement in the field of stroke. We’re excited about the results released today, offering the first level-one evidence that late and unwitnessed stroke patients who receive mechanical thrombectomy may have better outcomes,” said Mark Paul, president of Stryker’s neurovascular division. “Today, only a very small portion of the patient population is treated with a stent retriever. Data from this trial may result in changes to patient selection, allowing more stroke patients to receive endovascular treatment.”

Even with the results from the DAWN Trial, there is still significant work required to ensure patients receive fast and effective treatment for stroke. Best outcomes are achieved when patients are treated as quickly as possible, requiring increased patient awareness, EMS outreach and hospital infrastructure to be in place.

About the Trevo Retriever
Stryker’s Trevo Retriever is a tiny stent-shaped medical device that is attached to a thin wire. In a minimally invasive procedure that utilizes X-ray, the physician navigates the retriever from the femoral artery (located in the upper leg) to the blocked blood artery in the brain. The retriever is designed to ensnare the blood clot and remove it from the body. Originally cleared by the FDA in 2012 for the revascularization of patients experiencing ischemic stroke, the Trevo Retriever has been used in thousands of patients worldwide. The retriever’s indication within the DAWN Trial, for use in patients treated six to 24 hours after last seen well, is currently approved for investigational use only by the U.S. Food and Drug Administration in the United States under an Investigational Device Exemption (IDE) study approval. The Trevo Retriever is currently indicated for treatment up to eight hours from symptom onset. It was the only mechanical thrombectomy device used in the DAWN Trial.

An animation of Stryker’s Trevo Retriever is available here: https://youtu.be/PxcERzyI67I

About ischemic stroke
An ischemic stroke occurs when an artery in the brain becomes blocked by a blood clot or other substance such as plaque, a fatty material. Blood vessels carry blood, oxygen and nutrients throughout the body and to the brain. When the brain is deprived of blood and oxygen, it fails to work properly. Depending on the severity of the stroke and the area of the brain affected, loss of brain function or death may occur. According to the World Heart Federation, ischemic stroke contributes to nearly six million deaths around the globe annually.1

About Stryker
Stryker is one of the world's leading medical technology companies and, together with our customers, we are driven to make healthcare better. The Company offers a diverse array of innovative products and services in Orthopedics, Medical and Surgical, and Neurotechnology and Spine that help improve patient and hospital outcomes. Stryker is active in over 100 countries around the world. Please contact us for more information at www.stryker.com.

* Severe disability defined as mRS score of 3-6 and requiring assistance to perform activities of daily living.
† Compared to results from the following clinical trials: ESCAPE, EXTEND-IA, MR CLEAN, REVASCAT, SWIFT PRIME, THRACE

1. www.world-heart-federation.org/cardiovascular-health/stroke. Accessed May 12, 2017.

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