Hip Innovation Technology Receives FDA Approval to Initiate Landmark Study of its Reverse Hip Replacement System

HIT's Reverse Hip Replacement System May Revolutionize Total Hip Replacement Surgery

BOCA RATON, FLORIDA, January 18, 2022 -- Hip Innovation Technology, LLC (HIT), a medical device company developing innovative orthopedic device solutions to advance the quality of life and quality of care for patients, has received FDA (Food and Drug Administration) Investigational Device Exemption (IDE) approval to initiate a pivotal clinical study to further evaluate the company's Reverse Hip Replacement System (HRS) for use in Primary Total Hip Arthroplasty (THA).

The clinical study objective is to evaluate the safety and effectiveness of the Reverse HRS in patients undergoing Total Hip Replacement. Safety will be assessed through the collection of device-related adverse events and patient quality of life metrics. Effectiveness will be evaluated using clinical, radiologic, and patient-reported outcomes.

"The Reverse HRS is a unique hip implant design that we believe represents a significant advancement for patients requiring total hip arthroplasty," said George Diamantoni, Hip Innovation Technology's Co-Founder and Chief Executive Officer. "In our pivotal study we will further evaluate potential HRS patient benefits including hip stability at extended ranges of motion, reduced risk of device dislocation, and greater latitude for placement of hip components."

In an ongoing 100-patient clinical study, the company has collected outcomes data from multiple sources including radio stereometric analysis (RSA). RSA is state-of-the-art x-ray technique used to evaluate device micro-motion and wear. Data from the first 21 patients demonstrates minimal migration between 12 and 24 months for both the femoral and acetabular components. Mean migration was below detection and no migration concern was identified among all study patients. Importantly, patient Recorded Outcome Measure (PROM) data suggest significant improvement from pre- to post-operative patient and physician perspectives.

"The Reverse HRS first phase RSA clinical data evaluating implant micro-motion of the acetabular and femoral components has demonstrated each to be at a "not at risk" category for aseptic loosening indicating predictable long-term fixation," said Steve MacDonald, MD, Professor and JC Kennedy Chairman of Orthopaedic Surgery at the University of Western Ontario in London, Ontario, Canada. "The FDA IDE trial that will begin in 2022 will further assess the Reverse HRS clinical performance in multiple sites, in the U.S."

Total hip replacements are one of the most effective ways to reduce joint pain and improve functioning for patients with advanced hip problems. According to the American Academy of Orthopaedic Surgeons (AAOS), over 450,000 hip replacements are performed each year in the U.S.

About the Reverse HRS

The Reverse HRS is a Metal-on-Polyethylene reverse geometry hip prosthesis designed to improve stability at extended ranges of motion and reduce the risk of dislocation. Like most conventional systems, the Reverse HRS consists of a femoral stem, an acetabular cup and a cobalt-chrome ball that articulates within a polyethylene liner. Unlike existing total hip replacement systems, the ball is placed on a trunnion within the acetabular cup instead of the femoral stem, and the polyethylene liner is attached to a femoral cup, which then attaches to the femoral stem, as opposed to the polyethylene liner being attached to the acetabular cup.

About Hip Innovation Technology, LLC

Hip Innovation Technology, founded in 2011, provides market-leading orthopedic device solutions that advances quality of life and quality of care for patients. In partnership with healthcare professionals worldwide, our goal is to design, manufacture and ultimately market innovative orthopaedic reconstructive and related surgical product solutions in areas of high unmet medical need.

For more information, visit www.hipinnovationtechnology.com.

Cautionary Statement Regarding Forward-Looking Statements

This news release may contain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements concerning Hip Innovation Technology's expectations, plans, prospects, and product and service offerings, including new product launches and potential clinical successes. Such statements are based upon the current beliefs and expectations of management and are subject to significant risks and uncertainties that could cause actual outcomes and results to differ materially. Hip Innovation Technology disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Accordingly, such forward-looking statements speak only as of the date made. Readers of this news release are cautioned not to place undue reliance on these forward-looking statements, since, while management believes the assumptions on which the forward-looking statements are based are reasonable, there can be no assurance that these forward-looking statements will prove to be accurate. This cautionary statement is applicable to all forward-looking statements contained in this news release.

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