Integra LifeSciences Announces First Patient Enrolled in Acclarent AERA® Pediatric Registry

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PRINCETON, N.J., July 02, 2025 (GLOBE NEWSWIRE) -- Integra LifeSciences Holding Corporation (Nasdaq: IART), a leading global medical technology company, is proud to announce enrollment of the first patient in the Acclarent AERA Pediatric Registry, a prospective, multi-center observational registry evaluating the real-world use of the AERA Eustachian Tube Balloon Dilation System in children.

Acclarent AERA® Eustachian Tube Balloon Dilation System



First Patient Enrolled in Acclarent AERA® Pediatric Registry

This inaugural enrollment marks the focused effort to measure the ongoing, real-world clinical performance of AERA in pediatric patients with obstructive Eustachian tube dysfunction (ETD). Dr. Prasad Thottam at Michigan Pediatric ENT Associates enrolled the first patient; “We are proud to support this important initiative and even prouder that our team was the first to register a patient in the registry,” remarked Thottam.

The registry is designed to capture both safety and efficacy outcomes for up to 300 pediatric patients who undergo Eustachian tube balloon dilation (ETBD) using AERA. "In our ongoing commitment to better understand and treat pediatric Eustachian tube dysfunction and middle ear disease, the Acclarent AERA Pediatric Registry marks a critical advancement,” said Thottam. “This milestone reflects not only the field's dedication to improving pediatric ENT care, but also Integra’s commitment to advancing safe, evidence-based innovation in this space.”

The primary endpoint of the registry is a failure-free status following ETBD with the AERA device; failure being defined as the need for revision surgery, including additional ETBD procedures, tympanostomy tube placement or adenoidectomy due to ETD. Secondary endpoints include tympanogram results, pure tone audiometry, the Valsalva maneuver, inflammation scores, and patient-reported outcomes. The registry will also capture the rate of successful balloon dilation during procedures, and all adverse events or complications will be monitored as part of the safety assessment. Up to 20 sites across the U.S. are expected to participate in this registry. The data generated will provide valuable real-world insights into pediatric ETBD procedures and support broader efforts to improve reimbursement pathways and clinical adoption.

About Integra LifeSciences
At Integra LifeSciences, we are driven by our purpose of restoring patients’ lives. We innovate treatment pathways to advance patient outcomes and set new standards of surgical, neurologic, and regenerative care. We offer a comprehensive portfolio of high quality, leadership medical technology brands. For the latest news and information about Integra and its products, please visit www.integralife.com.

Forward-Looking Statements
This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ from predicted results. Forward-looking factors that may be discussed include, but are not limited to, the potential clinical application and efficacy of the AERA Eustachian Tube Balloon Dilation System in children, the number of patients and sites expected to be involved in the Acclarent AERA Pediatric Registry and the anticipated utility of data collected from the Acclarent AERA Pediatric Registry. There can be no assurance that the AERA Pediatric Registry will be able to meet the site, enrollment and observation objectives described herein or that any potential clinical applications and benefits will be observed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Integra’s business and market, particularly those identified under the heading "Risk Factors" included in item 1A of Integra's Annual Report on Form 10-K for the year ended December 31, 2024, and information contained in subsequent filings with the Securities and Exchange Commission. These forward-looking statements are made only as the date thereof, and Integra undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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