FDA Approves The World's Smallest Mechanical Heart Valve For Pediatric Patients With Heart Defects

- First and only pediatric mechanical heart valve developed to include newborns and infants

- Life-saving technology - the size of a dime - provides new treatment option to address unmet need

- Nearly one in four children with critical heart defects may require surgery or other procedures in their first year of life[1]

ABBOTT PARK, Ill., March 6, 2018 /PRNewswire/ -- Abbott today announced the U.S. Food and Drug Administration (FDA) approved the Masters HP™ 15mm rotatable mechanical heart valve, the world's smallest mechanical heart valve, that will allow doctors to treat babies and toddlers in need of a mitral or aortic valve replacement. Until today, surgeons could only use a range of larger-sized valves to replace a pediatric heart valve that could not be repaired, and larger valves are often not suitable given the smaller size of children's hearts. This dime-sized new valve is the first and only pediatric mechanical heart valve developed for newborns and infants, and offers hope for pediatric patients in urgent need of treatment who have no other approved options.

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In the U.S. alone, congenital heart defects (CHD) affect nearly 1 percent – about 40,000 – births each year[1]. For children who have a poorly functioning valve that cannot be repaired, a valve replacement procedure using Abbott's 15mm mechanical heart valve is now an option.

"In my practice, I want to be able to provide a treatment option that works for a critically ill child when a larger-sized valve may not be suitable," said Kirk R. Kanter, M.D., professor of surgery and director of the Heart Transplant Program at Children's Healthcare in Atlanta at Emory University School of Medicine, which was the top enrolling site for the trial that led to approval of this new treatment option. "The approval of this smaller pediatric mechanical heart valve provides surgeons with a much-needed option for treating these vulnerable, high-risk children."

The heart's mitral and aortic valves move blood through the heart, providing the body with oxygen-rich blood. Both valves, when functioning properly, open and close sequentially as blood enters and leaves the heart with each contraction. This forward transfer of blood is a critical process for the heart to function as intended[1], and when either valve doesn't work properly[2], the condition can lead to life-threatening heart failure.[3]

Sadie Rutenberg, now a 3-year-old, was only a few months old when her parents noticed she was breathing fast, stopped gaining weight and was not eating well due to a congenital heart problem.

"When we were told that Sadie would need surgery right away, and was a candidate for a new clinical trial of a heart valve sized for her small body, we were willing to try it to hopefully save her life," said Lee'or Rutenberg, Sadie's father. "When the doctor came out of surgery and told us the surgery was a success – as a parent, it's a moment I'll never forget. The valve saved Sadie's life."

When the tissues of the heart valve have a significant malformation or are too damaged and cannot be repaired to function properly, it may be necessary to replace the valve with a mechanical valve. A mechanical heart valve mimics the valve of a healthy heart, opening and closing with each heartbeat, permitting proper blood flow through the heart.

"There's an urgent need for the smallest babies and children who need a suitable replacement valve in order to survive," said Michael Dale, vice president of Abbott's structural heart business. "Abbott's new mechanical pediatric heart valve is a life-changing technology for the smallest pediatric patients, giving them a better chance at a long, healthy life with a fully functioning heart."

The approval of Abbott's new Masters HP™ 15mm rotatable mechanical heart valve was primarily based on the results of a clinical trial, which enrolled pediatric patients five years of age or younger who had a diseased, damaged or malfunctioning heart valve. Jonathan M. Chen M.D., co-director of the Seattle Children's Hospital Heart Center and division chief for pediatric cardiothoracic surgery, was the first physician in the trial to implant the Masters HP 15mm valve in a pediatric patient. Dr. Chen treated Sadie Rutenberg, who was the first infant to undergo the treatment in the clinical trial. She is now a healthy 3-year-old. Click here for more details on Sadie's story.

About Abbott's Pediatric Mechanical Heart Valve
The Masters HP™ 15mm rotatable mechanical heart valve is a rotatable, bileaflet mechanical heart valve designed for implantation in the mitral or aortic position and is part of the Masters Series line, which now includes seven valves with diameter sizes ranging from 15 to 27mm.

Initially approved in 1995, the valves have pyrolytic carbon leaflets and orifice rings, an 85-degree leaflet opening angle to improve flow and reduce turbulence, and a controlled torque rotation mechanism for rotation and intraoperative adjustment. A sewing cuff contains additional suture markers for more accurate placement.

For U.S. Important Safety Information on the Masters HP Series, visithttp://abbo.tt/2taeyVL.

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[1] Centers for Disease Control and Prevention. Congenital Heart Defects. Available https://www.cdc.gov/ncbddd/heartdefects/data.html. Accessed on January 26, 2018.

[2] Healthline Medical Team. Available at https://www.healthline.com/human-body-maps/mitral-valve. Accessed January 26, 2018.

[3] The Society of Thoracic Surgeons. Mitral Valve Disease. Available at https://ctsurgerypatients.org/adult-heart-disease/mitral-valve-disease. Accessed January 26, 2018.

[4] Healthline. What is mitral valve disease? Available at https://www.healthline.com/health/mitral-valve-disease#overview1. Accessed January 26, 2018.

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