FDA Approves Labeling Update For Abbott's HeartMate 3 Heart Pump For Use In Pediatric Patients

- Abbott's HeartMate 3™ heart pump approved for use for pediatric patients battling advanced heart failure

- This life-saving technology provides new treatment option for underserved population

ABBOTT PARK, Ill., Dec. 17, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the U.S. Food and Drug Administration (FDA) has approved updated labeling for the company's HeartMate 3™ heart pump to be used in pediatric patients with advanced refractory left ventricular heart failure. With the updated labeling, physicians now have additional options for treating this underserved population awaiting a heart transplant or for those not eligible to receive a transplant as a result of potential complications or risk related to the procedure.

The approval follows similar pediatric innovations for Abbott in recent years, including the Masters HP™, a 15mm pediatric heart valve the size of a dime, approved in 2018; and the Amplatzer Piccolo™ Occluder, a pea-sized plug approved in 2019 to help treat a potentially life-threatening opening in the heart of some premature or newborn babies.

Many children and adolescents with congestive heart failure require a heart transplant or mechanical device implant to survive. The HeartMate 3 left ventricular assist device (LVAD) – or heart pump – is an implantable device that pumps blood through the body in people whose heart is too weak to do so on its own. The HeartMate 3 pump was initially approved in the United States in 2017 for adults awaiting a heart transplant and received FDA approval for long-term use in adults in 2018. In the largest LVAD trial in the world, the HeartMate 3 pump showed a survival rate of 79% at two years – an outcome comparable to patients receiving a heart transplant.

"For families with children battling chronic diseases the future is often bleak. As physicians, we see the fear in the eyes of not only the child, but also the mothers and fathers," said Robert L. Kormos, M.D., divisional vice president, global medical affairs, Abbott's heart failure business. "Imagine a child with a heart condition that does not allow them to play with friends, sing or run. Innovations, such as the HeartMate 3, can lessen the crippling effects of heart failure and allow that child to live a more normal life."

LIFE-CHANGING COLLABORATION IN ACTION

The updated labeling for HeartMate 3 to be used in pediatric patients was supported by clinical data from the Advanced Cardiac Therapies Improving Outcomes Network (ACTION Learning Collaborative), a consortium of 50+ U.S. pediatric hospitals that pooled together data to show advantageous outcomes of the HeartMate 3 in pediatric patients.

"Our mission is to improve the outcomes of children with heart failure. Historically, this has been an underfunded and understudied area in pediatrics," said Angela Lorts, M.D., M.B.A., and David Rosenthal, M.D., co-founders of ACTION Learning Collaborative. "This technology will benefit our pediatric patients and is a leap forward for improving heart failure outcomes in children. We are honored to collaborate with Abbott on this pediatric initiative."

BACK TO LIVING LIFE ON HER TERMS

Katrina Sellens, now 16-years-old, was an active teenager before being diagnosed with cardiomyopathy, a serious disease of the heart muscle that can lead to heart failure. She couldn't walk 10 feet without feeling exhausted and had to bend over just to breathe. In 2019, Katrina received the Abbott HeartMate 3 under a special request to treat her life-threatening disease.

"One of the most depressing aspects of heart failure is seeing your child lose the ability to do what had always come naturally," said Maria Bautista, Katrina's mother. "I didn't believe she would get as strong as she has with the HeartMate 3. We are back to living life on her terms."

Nearly two years later, Katrina is back to camping and taking care of her family's chickens. The high school sophomore recently earned her driver's permit and dreams of becoming an LVAD nurse so she can help others with heart failure. For more on Katrina's story, click here.

Resources to Learn More

Heart failure is a manageable condition, especially if it is detected early. Cardiologists and other healthcare providers can visit Abbott Cardiovascular for more resources on the latest innovations and solutions designed for patients with heart failure.

About Abbott's HeartMate 3 heart pump

Abbott's HeartMate 3™ heart pump is a small, implantable mechanical circulatory support device for advanced heart failure patients who are awaiting transplantation or are not candidates for heart transplantation. It is the first commercially approved (CE Mark and FDA approved) heart pump with Full MagLev™ technology, which allows the device's rotor to be "suspended" by magnetic forces. This design aims to reduce trauma to blood passing through the pump and improve outcomes for patients.

For U.S. important safety information for the HeartMate 3, visit https://www.cardiovascular.abbott/us/en/campaigns/heartmate-3-

lvad-pediatric.html.

For U.S. important safety information for the Masters HP Series, visit http://abbo.tt/2taeyVL.

For U.S. important safety information for the Amplatzer Piccolo Occluder, visit https://www.structuralheartsolutions.com/us/piccolo-ISI.

About Abbott

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