Abbott Announces European Approval Of Two Life-Saving Heart Devices For Babies And Children

- World's smallest pediatric treatments pioneered by Abbott address critical needs for the most vulnerable patients: babies and children born with common congenital heart defects

- Includes pediatric mechanical heart valve and first minimally invasive device to treat premature babies and newborns born with an opening in their heart

ABBOTT PARK, Ill., Sept. 17, 2019 /PRNewswire/ -- Abbott (NYSE: ABT) today announced approvals in Europe for two of its life-saving pediatric devices. The Masters HP™ 15mm rotatable mechanical heart valve and the Amplatzer Piccolo™ Occluder have received CE Mark and are now available in Europe and other countries that recognize CE Mark. The new treatments, already available in the U.S., offer young pediatric patients and their families hope when no other suitable treatment option may exist.

Congenital heart defects (CHD) affect approximately 36,000 births in the European Union each year[i]. The Masters valve is the world's smallest mechanical heart valve and allows doctors to treat babies and toddlers in need of a mitral or aortic heart valve replacement. The Amplatzer Piccolo is smaller than a pea and is the world's first medical device that can be implanted in the tiniest babies (weighing as little as under one kilogram) to treat patent ductus arteriosus, or PDA, a potentially life-threatening opening in the heart. These life-saving devices for certain congenital heart defects are the first and only devices of their kind.

"Devices like these are among the best examples of our promise at Abbott to help people live their fullest lives – in this case, young babies and children for whom these treatments are nothing short of miraculous," said Michael Dale, vice president of Abbott's structural heart business. "While the children who benefit from these therapies represent a very small segment of the total population with structural heart disease, these advanced technologies enable physicians to treat vulnerable pediatric patients who otherwise have limited options."

About the Masters HP 15mm Rotatable Mechanical Heart Valve

Smaller than a 1c euro, at just 15mm the Masters valve is the first and only pediatric mechanical heart valve developed for newborns and infants and is now available in the European Union. The 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.

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 a healthy heart valve, opening and closing with each heartbeat, permitting proper blood flow through the heart.

Until Abbott's device, surgeons could only use a range of larger-sized valves to replace a pediatric heart valve that could not be repaired, which could result in improper fit and complications. The Masters pediatric valve was approved in the United States in March 2018 and in Canada in October 2018.

About the Amplatzer Piccolo Occluder

One of the most common congenital heart defects occurring in premature babies, PDA, is a potentially life-threatening opening between two blood vessels which lead from the heart. This channel, which is present in normally developing fetuses, is important prior to birth to allow oxygen-rich blood from the mother to circulate throughout the fetus' body. For most infants, the pathway, or duct, seals itself shortly after birth. In some cases, primarily in babies born prematurely, the PDA fails to spontaneously close, which can make it difficult for babies to breathe normally due to increased blood flow to the lungs. PDA accounts for up to 10% of all congenital heart disease.[ii]

The Amplatzer Piccolo, approved in the U.S. in January 2019, is a self-expanding, wire mesh device that is inserted through a small incision in the leg and guided through vessels to the heart, where it is placed to seal the opening in the heart. Many of the premature babies who are critically ill in the neonatal intensive care unit are able to be weaned from artificial respirator support soon after the minimally invasive procedure. With the approval of the Amplatzer Piccolo in Europe and other countries that recognize CE Mark, Abbott offers hope to premature infants and newborns who need corrective treatment, and who may be non-responsive to medical management and high risk to undergo corrective surgery.

The Amplatzer Piccolo device builds on more than 20 years of clinical success for Abbott's family of Amplatzer Occluder therapies, including the Amplatzer™ Duct Occluder family of products (ADO, ADOII and ADOIIAS), already approved for use in Europe and countries around the world to treat PDA in larger size pediatric patients.

"Seeing the youngest patients fight for their lives is harrowing, and finally having solutions that can offer a dependable treatment option to get these little ones out of the NICU and sent home with their families is a huge advance in our field," said Dr. Mario Carminati, Director of Pediatric and Adult Congenital Cardiology at IRCCS Policlinico San Donato, Milan.

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

For U.S. Important Safety Information about the Amplatzer Piccolo Occluder, visit https://www.structuralheartsolutions.com/us/piccolo-ISI.

About Abbott
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[i] Dolk, Helen et al. "Congenital heart defects inEurope: prevalence and perinatal mortality, 2000 to 2005." *Circulation* 123 8 (2011): 841-9.

[ii] Schneider, D. J., & Moore, J. W. (2006). Patent ductus arteriosus. Circulation, 114(17), 1873-18.

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