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Tokyo:Ã?Â United Kingdom's Mallinckrodt plc has announced that INOmax (nitric oxide) for inhalation has received regulatory approval in Australia and Japan for pulmonary hypertension in conjunction with heart surgery.

INOmax is claimed to be the first pharmaceutical gas approved in both Australia and Japan in 2007 and 2008, respectively, for the treatment of hypoxic respiratory failure (HRF), a potentially life-threatening condition in newborns.

INOmax is approved in the United States to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

The Australian Therapeutic Goods Administration (TGA) has approved INOmax for peri- and post-operative pulmonary hypertension in conjunction with cardiovascular surgery in neonates through adolescents up to age 17. INOmax was approved in 2007 for the treatment of hypoxic respiratory failure (HRF) associated with pulmonary hypertension, a potentially life-threatening condition in newborns.

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Japan's Ministry of Health, Labour and Welfare (MHLW) has approved INOmax, marketed as INOflo/INOvent in Japan, for peri-operative pulmonary hypertension in conjunction with cardiovascular surgery for use in neonates through adults.
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INOmax is a vasodilator that opens (dilates) blood vessels, improving oxygen uptake and blood flow. It is used in conjunction with ventilator support and other appropriate agents. INOmax decreases pulmonary arterial pressure and improves oxygenation.

"The approval of INOmax in Australia and Japan for cardiovascular surgery represents a significant milestone for Mallinckrodt and INOmax," said Tom Englese, General Manager, Mallinckrodt. "Worldwide, there is a tremendous need for therapies for

patients undergoing cardiac surgery. We look forward to helping meet these needs while broadening our reach in global markets."