PRESS RELEASE

Chiesi USA Announces Publication of Health Economics Analysis of Selective Early Rescue Surfactant Administration vs. Standard Surfactant Administration for Premature Infants with Respiratory Distress Syndrome

- This cost-consequence analysis suggests selective early rescue surfactant administration strategies are associated with a lower healthcare burden in premature infants with RDS.

Cary, North Carolina, November 29, 2022 – Chiesi USA (key-ay-zee), the U.S. affiliate of Chiesi Farmaceutici, an international research-focused healthcare group (Chiesi Group), today announced the publication of an article describing a health economic model comparing selective early rescue surfactant administration versus standard surfactant administration for infants with respiratory distress syndrome (RDS). The paper appears in the online November/December 2022 edition of *The Journal of Pediatric Pharmacology and Therapeutics*.

The objective of the health economic model is to quantify the impact of early rescue surfactant administration for preterm infants with RDS from a healthcare delivery system perspective. The model compares the clinical and economic impact of early surfactant administration versus standard surfactant administration across a one-year horizon (one year of patient volume) in infants for whom surfactant treatment was indicated (FiO2 = 0.3). Early selective surfactant administration, such as use of the INtubation SURfactant Extubation (INSURE)* technique was compared to a base case of standard surfactant administration via endotracheal intubation and mechanical ventilation.

As a simplifying model assumption, CUROSURF® (poractant alfa) was assumed to be the surfactant used in all treatment strategies. CUROSURF Intratracheal Suspension is a surfactant indicated for the rescue treatment, including the reduction of mortality and pneumothoraces, of respiratory distress syndrome (RDS) in premature infants.

The authors' conclusions suggest that selective early rescue surfactant administration strategies are associated with a lower healthcare burden in premature infants with RDS.

"There has been much discussion about treatment decisions for premature infants with RDS," said Marc Claussen, Vice President, Value & Market Access at Chiesi USA. "Based on this analysis, we are pleased to find that the use of selective early surfactant led to expected overall cost savings in total hospital and complications costs. We hope that the conclusions of this analysis can add evidence of the economic benefits of early surfactant administration strategies."

*It is important to note that the INSURE strategy may not be appropriate for all infants. Infants with RDS may vary markedly in the severity of respiratory disease, maturity, and presence of other complications, and thus it is necessary to individualize patient care.

Please be aware that the results from this study are provided as Health Economic and Value Information, which can be provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of healthcare economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement.

Indication

CUROSURF® (poractant alfa) Intratracheal Suspension is indicated for the rescue treatment of Respiratory Distress Syndrome (RDS) in premature infants. CUROSURF reduces mortality and pneumothoraces associated with RDS.

Important Safety Information

CUROSURF® (poractant alfa) is intended for intratracheal use only. The administration of exogenous surfactants, including CUROSURF, can rapidly affect oxygenation and lung compliance. Therefore, infants receiving CUROSURF should receive frequent clinical and laboratory assessments so that oxygen and ventilatory support can be modified to respond to respiratory changes.

CUROSURF should only be administered by those trained and experienced in the care, resuscitation, and stabilization of preterm infants.

Transient adverse reactions associated with administration of CUROSURF include bradycardia, hypotension, endotracheal tube blockage, and oxygen desaturation. These events require stopping CUROSURF administration and taking appropriate measures to alleviate the condition. After the patient is stable, dosing may proceed with appropriate monitoring.

Pulmonary hemorrhage, a known complication of premature birth and very low birth-weight, has been reported with CUROSURF. The rates of common complications of prematurity observed in a multicenter single-dose study that enrolled infants 700–2000 g birth weight with RDS requiring mechanical ventilation and FiO2 ≥ 0.60 are as follows for CUROSURF 2.5 mL/kg (200 mg/kg) (n=78) and control (n=66; no surfactant) respectively: acquired pneumonia (17% vs. 21%), acquired septicemia (14% vs. 18%), bronchopulmonary dysplasia (18% vs. 22%), intracranial hemorrhage (51% vs. 64%), patent ductus arteriosus (60% vs. 48%), pneumothorax (21% vs. 36%) and pulmonary interstitial emphysema (21% vs. 38%).

Please see Full Prescribing Information.

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About Chiesi USA
Chiesi USA, Inc., headquartered in Cary, North Carolina, is a specialty pharmaceutical company focused on commercialization of products for the hospital and target office-based specialties. The Company is a wholly-owned subsidiary of family-owned Chiesi Farmaceutici S.p.A, a global R&D-focused pharmaceutical company based in Parma, Italy. In the United States, the Company delivers therapies and enhances care for patients in the areas of acute cardiology, neonatology, cystic fibrosis and rare diseases. Recognized as a Certified B Corporation™, Chiesi is dedicated to improving the health and well-being of its communities through its employee-led corporate social responsibility program, Chiesi in the Community. Innovation, collaboration and impact are the cornerstones of the Chiesi culture. For more information, visit www.chiesiusa.com.

About Chiesi Group
Chiesi is an international, research-focused biopharmaceuticals group that develops and markets innovative therapeutic solutions in respiratory health, rare diseases, and specialty care. The company's mission is to improve people's quality of life and act responsibly towards both the community and the environment.

By changing its legal status to a Benefit Corporation in Italy, the US, and France, Chiesi's commitment to create shared value for society as a whole is legally binding and central to company-wide decision-making. Since 2019 Chiesi is certified B Corp, meaning that its sustainability efforts are measured and assessed by the most ambitious global standards. The company aims at becoming net-zero by 2035.

With over 85 years of experience, Chiesi is headquartered in Parma (Italy), operates in 30 countries, and counts more than 6,000 employees. The Group's research and development centre in Parma works alongside 6 other important R&D hubs in France, the US, Canada, China, the UK, and Sweden.

For further information please visit www.chiesi.com.

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