Aerogen Pharma and Lyomark Pharma partner to develop inhaled surfactant, begin a Phase 2 clinical trial

an alliance to improve lung disease treatment in premature birth

GALWAY, IRELAND & OBERHACHING, GERMANY - DECEMBER 7, 2017: Aerogen Pharma, a developer of innovative inhaled treatments for patients in critical care, and Lyomark Pharma, an established provider of high-quality medicines for the hospital market, are joining forces to develop a clinically superior treatment for Respiratory Distress Syndrome (RDS), a life-threatening condition of preterm infants associated with long-term lung health issues in survivors.

AP-002 is a nasally inhaled surfactant based on a combination of Lyomark's Alveofact® (bovine lung surfactant) and Aerogen's next generation "PDAP™" delivery technology. The partners expect **AP-002** to set a new standard in the treatment of RDS, since it will enable surfactant administration via the nose and complement current first line therapy with nasal continuous positive airway pressure ventilation (nCPAP). **AP-002** is anticipated to reduce the need for sedation, invasive intubation and mechanical ventilation, all features of current surfactant treatment methods associated with adverse side effects and the potential to exacerbate chronic lung disease in preterm infants.

The PDAP™ delivery system is a technical breakthrough based on patented enhancements to Aerogen's market-leading aerosol generator technology (www.aerogen.com), which effectively nebulizes surfactant and enables this potentially major advance in therapy. Alveofact® is sold as an RDS treatment in 27 countries, with a proven record of safety and efficacy when administered by conventional instillation techniques and class-leading, three-year room temperature stability. Aerogen will adapt Alveofact® for inhaled delivery, and the partners will work together to commercialise and distribute **AP-002** around the world.

AP-002 advanced to clinical trials

In a further development, Aerogen Pharma announced the initiation of a Phase 2 clinical study at three major maternity hospitals in Australia. This trial will evaluate the safety and effectiveness of **AP-002** relative to standard invasive surfactant administration in preterm infants with symptoms of RDS. Details of this study are available at www.anzctr.org.au under Trial ID ACTRN12617001458325, and results are expected mid-2018.

Dr Andy Clark, Vice President and General Manager of Aerogen Pharma Corporation, commented: "We are grateful to the dedicated Australian medical teams involved in our first clinical investigation of **AP-002**, which has the potential to be a major advance in the care of these precious and highly vulnerable patients".

Lyomark Pharma's Managing Director, Malik Malocho, said: "While surfactant therapy saves lives, today's invasive methods of administration are often associated with adverse side effects that limit its use. We believe that Lyomark's drug and Aerogen's delivery system, in combination, will uniquely benefit patients by avoiding these complications and limitations".

About Aerogen Pharma

Aerogen Pharma is an Irish specialty pharmaceutical company developing inhaled products for quick, efficient, consistent and user-friendly treatment of critically ill patients in hospital acute care. Aerogen Pharma improves existing drugs by targeting them to the lung using a proprietary, high performance aerosol delivery system based on the market-leading nebuliser technology created by the Aerogen group. For more information, visit www.aerogen.com/aerogen-pharma/.

About Lyomark Pharma

Lyomark is a German pharmaceutical company specialised in niche proprietary and generic products and orphan drugs for rare diseases, presented as sterile injectable, lyophilized formulations in pre-filled syringes, vials and ampoules. Lyomark's Alveofact® lung surfactant has been in clinical use for twenty years as a treatment for neonatal RDS, with established safety and efficacy. For more information, visit www.lyomark.com.

About Respiratory Distress Syndrome

RDS is a lung condition that affects newborn babies, usually those that are born 6 or more weeks before their due dates ("preterm infants"). This is because an infant's lungs do not start making surfactant until late in gestation. Surfactant is a liquid that coats the inside of the lungs and helps keep the airways open so that the infants can breathe air after birth. The lungs of babies born prematurely contain too little surfactant and are prone to collapse on exhalation. The infant has to work much harder to breathe and may not get enough oxygen, leading to damage to the lungs, brain and other organs. To combat this, preterm infants are given respiratory support with nCPAP, which helps hold the lungs open on exhalation and prevent collapse. Infants may receive supplementary oxygen, and if respiratory distress persists may receive surfactant replacement therapy to supply the surfactant they lack. Serious complications of RDS, or its treatment, include respiratory problems such as asthma and BPD, blindness, and brain damage. For more information, see for example https://www.nhlbi.nih.gov/health/health-topics/topics/rds.

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