Chiesi Group and Oak Hill Bio announce License and Development Agreement to develop, manufacture, and commercialise OHB-607, a potentially transformative neonatal therapy

- Chiesi Group and Oak Hill Bio will collaborate closely to develop OHB-607, a clinical-stage investigational drug candidate being developed to treat complications of extremely premature birth.
- This agreement expands Chiesi's commitment to Neonatology, a highly strategic area for the company.
- Partners intend to continue Phase 2b clinical trial of OHB-607 in 2024.

MANCHESTER, UK, 9th January 2024 – Chiesi Farmaceutici S.p.A ("Chiesi Group"), an international, research-focused biopharmaceuticals and healthcare group, and Oak Hill Bio, a clinical-stage neonatology and rare disease therapeutics company, today announced the execution of a License and Development Agreement to develop, manufacture, and commercialise OHB-607, an investigational drug candidate being developed to treat complications of extremely premature birth.

OHB-607 is a recombinant version of insulin-like growth factor-1 (IGF-1), a key driver of foetal growth and development, and its binding protein, IGFBP-3. For the developing foetus, mothers are the primary source of IGF-1. Babies born at less than 28 weeks gestational age have low levels of IGF-1 and face high risk of severe bronchopulmonary dysplasia (BPD), which may lead to chronic lung disease. There are currently no approved medicines to prevent BPD in pre-term infants. OHB-607, a human IGF-1 replacement, is designed to help prevent BPD and its long-term respiratory consequences.

"BPD represents a challenging complication of prematurity for which there is currently no available treatment. Innovative solutions are needed, and the therapy may provide a solution for a disease with one of the highest unmet medical needs in the field of neonatology," commented Ralph Blom, General Manager, Chiesi UK and Ireland.

Chiesi and Oak Hill Bio intend to continue a Phase 2b clinical trial in 2024 in the United States, Europe, and Japan. Clinical studies conducted to date have demonstrated OHB-607's potential to significantly reduce the risk of severe BPD.[1]

"*We hope that OHB-607 will lead to improved outcomes for extremely preterm infants at risk of severe BPD and subsequently chronic lung disease*," said Josh Distler, President, and Chief Financial Officer of Oak Hill Bio. "*We are thrilled to partner with Chiesi. Their deep expertise in neonatology will help to rapidly advance this promising therapy to patients.*"

Guggenheim Securities LLC acted as exclusive financial advisor to Oak Hill Bio and Goodwin Procter LLP served as its legal advisor.

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About Bronchopulmonary Dysplasia (BPD)[2]

Bronchopulmonary dysplasia (BPD) is a form of chronic lung disease affecting newborns who are born prematurely, particularly those who are exposed to oxygen therapy or have required the use of a breathing machine for a long time. Due to their immaturity, the lungs of premature newborns are particularly vulnerable and may undergo abnormal development in the postnatal period; in particular, high amounts of inhaled oxygen and pressure may overstretch the alveoli, causing inflammation and damage to the inside lining of the airways, the alveoli and the blood vessels around them.

1 Ley D, Hallberg B, Hansen-Pupp I, et al. rhIGF-1/rhIGFBP-3 in Preterm Infants: A Phase 2 Randomized Controlled Trial. J Pediatr. 2019;206:56-65.e8. doi:10.1016/j.jpeds.2018.10.033

[2] Thébaud B, Goss KN, Laughon M, et al. Bronchopulmonary dysplasia. Nat Rev Dis Primers. 2019 Nov 14;5(1):78

The degree of prematurity in an infant is largely what puts a child at risk of developing BPD. The majority of newborns who develop BPD are born more than 10 weeks early, weigh less than two pounds at birth, and are born with breathing problems. BPD is rare in infants born after 32 weeks of pregnancy.

BPD is the most common respiratory complication of premature infants affecting on average 40-50% of those born at gestational age below 28 weeks, which might lead to increased mortality, hospitalisation rate and cost burden, as well as long-term respiratory morbidity with lifelong impact on respiratory function.

About OHB-607

OHB-607 is a complex of a recombinant version of insulin-like growth factor-1 (IGF-1) formulated with its binding protein for prevention of bronchopulmonary dysplasia in preterm infants. IGF-1 is a growth factor critical for organ growth and development in the foetus. Mothers are the primary source of IGF-1 for the developing foetus until reaching about 30 weeks gestational age. IGF-1 levels typically rise in the third trimester while the level of this protein is low in infants born prematurely due to loss of maternal source of IGF-1. Natural history studies document the association of lower IGF-1 concentrations with BPD in very preterm infants and provide rationale for IGF-1 treatment to restore levels which would have been present in case of a full-term pregnancy, supporting lung development.[3]

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. As a certified B Corp since 2019, we're part of a global community of businesses that meet high standards of social and environmental impact. The company aims to reach Net-Zero greenhouse gases (GHG) emissions by 2035.

With over 85 years of experience, Chiesi is headquartered in Parma (Italy), operates in 31 countries, and counts more than 6,500 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.uk.com

About Oak Hill Bio

Oak Hill Bio is a clinical-stage neonatology and rare disease therapeutics company developing life-changing medicines for extremely preterm infants and patients suffering from rare autoimmune diseases. The company, which has operations in the United States and United Kingdom, is advancing a pipeline of six promising clinical-stage and preclinical investigational therapeutics acquired and licensed from Takeda Pharmaceutical Company Limited ("Takeda"). For more information, visit the company's website at www.oakhillbio.com.

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[3] Kramer BW, Abman S, Daly M, et al. Insulin-like growth factor-1 replacement therapy after extremely premature birth: An opportunity to optimize lifelong lung health by preserving the natural sequence of lung development. Paediatr Resp Rev 2023 May 6:S1526-0542(23)00020-9