

Chiesi Group signed a License Agreement with Haisco Pharmaceutical to develop, manufacture, and commercialise a novel, reversible dipeptidyl peptidase 1 inhibitor for bronchiectasis

- Chiesi Group and Haisco Pharmaceutical will collaborate closely to develop HSK31858, a novel reversible dipeptidyl peptidase 1 (DPP1) inhibitor for respiratory diseases.
- This agreement expands Chiesi's R&D program in bronchiectasis, a respiratory disease with high unmet medical needs, for which no approved treatment is available to date.
- Haisco Pharmaceutical will receive an upfront payment and future milestone payments, including royalties on product sales.

Parma, Italy and Chengdu, China, November 20th, 2023 - Chiesi Farmaceutici S.p.A ("Chiesi Group"), an international, research-focused biopharmaceuticals and healthcare group, and Haisco Pharmaceutical Group Co.Ltd (Haisco Pharmaceutical) today announced the execution of a Licensing Agreement to develop, manufacture, and commercialise outside China and adjacent territories (Hong Kong SAR, Macau SAR and Taiwan District) HSK31858, a novel, reversible dipeptidyl peptidase 1 (DPP1) inhibitor for respiratory diseases.

HSK31858 is an oral, potent, and highly selective small molecule DPP1 inhibitor currently in Phase 2 trials in China with the potential to be an anti-inflammatory agent in bronchiectasis. With this agreement Chiesi will expand its product portfolio in its strategic respiratory field, aiming to further increase its impact in this area and contribute to developing treatments for severe respiratory diseases with high unmet medical needs.

"This collaboration demonstrates our commitment to develop new medicines aimed at improving the lives of patients who suffer from severe respiratory diseases with limited treatment options," commented **Thomas Eichholtz**, Head of Global Research and Development at Chiesi Group. *"HSK31858 is an important addition to our pipeline, and it offers a great opportunity to combine the two partners' strong experience in this field."*

"This collaboration with Chiesi is an important milestone in our globalisation strategy, we are pleased that HSK31858 will benefit patients worldwide in the future" said **Xiulian Fan**, General Manager at Haisco Pharmaceutical. *"We acknowledge and appreciate Chiesi's significant commitment and expertise in the development of drugs in the respiratory field and believe that this partnership will help maximise the value of HSK31858"*.

Under the terms of the agreement, Chiesi will make an upfront payment and additional contingent milestone payments to Haisco, including royalties on product sales.

###

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 bronchiectasis

Bronchiectasis refers to a heterogeneous and increasingly prevalent pulmonary disease characterised by symptoms like cough, sputum production and bronchial infection, and radiologically by abnormal and permanent dilatation of the bronchi¹. From a pathophysiological perspective, airway architectural changes lead to mucus accumulation, chronic airway infection and persistent neutrophilic inflammation which ultimately result in a vicious cycle of remodeling and dilation of the airways².

About dipeptidyl peptidase 1 (DPP1) inhibitor

In bronchiectasis, excessive neutrophil accumulation in the airways leads to neutrophil serine proteases (NSPs) release, which contributes to tissue damage and perpetuates the inflammatory process in the lungs. The three main NSPs include neutrophil elastase (NE), proteinase 3, and cathepsin G. Elevation in NE activity in sputum in bronchiectasis is associated with increased exacerbations and declines in lung function³. Dipeptidyl peptidase 1 (DPP1), an enzyme primarily found in neutrophils, is responsible for activating NSPs during neutrophil maturation in the bone marrow⁴.

About Haisco

Haisco Pharmaceutical is a publicly listed pharmaceutical company (002653.SZ) focusing on innovative drug R&D, integrating production, manufacturing, and sales promotion. The company is headquartered in Chengdu, China. Haisco has developed globally advanced technology platforms such as protein degradation and PDC, focusing on establishing a series of drug pipelines in the fields of perioperative, tumor, immune, respiratory, diabetes and complications. So far, one innovative drug has been approved for marketing, three innovative drugs have submitted NDA, and multiple innovative drugs are in the clinical trial. With the comprehensive innovation capabilities, Haisco has been awarded the title of "China's Innovative Pharmaceutical Enterprise in 2022" and has won numerous honors such as "Best Industrial Enterprise in China's Pharmaceutical R&D Pipelines" and "Top 100 Pharmaceutical Industry in China" for many years. The company was also selected as one of the "Top 100 Innovative Pharmaceutical Enterprises in China in 2021" and ranked in the first tier, as well as being listed in Forbes' 2021 China's Top 50 Most Innovative Enterprises list.

Further information can be found on haisco pharmaceuticals main website, available at: <http://en.haisco.com/>

Disclaimer

This press release contains forward-looking statements. While Haisco Pharmaceutical consider the projections to be based on reasonable assumptions, these forward-looking statements may be called into question by several hazards and uncertainties, so that actual results may differ materially from those anticipated in such forward-looking statements.

Media Contacts**Media Contacts**

Yasmin Ghariani, Chiesi UK
Head of External Communications
Phone: (+44) 161 488 5555
Email: y.ghariani@chiesi.com

Sarah Pollard, M+F Health
Account Director
Phone: (+44) 793 9002465
Email: sarah.pollard@mandfhealth.com

Bibliography:

1. Diagnosis and management of non-cystic fibrosis bronchiectasis, Macfarlane L. et al., Clinical Medicine 2021 Vol 21, No 6: e571-7
2. Anne E. O'Donnell, N Engl J Med 2022; 387:533-545
3. Neutrophil Elastase Activity Is Associated with Exacerbations and Lung Function Decline in Bronchiectasis, JD Chalmers et al, Am J Resp Crit Care Med 2017, 195(10):1384-1393
4. Dipeptidyl peptidase I activates neutrophil-derived serine proteases and regulates the development of acute experimental arthritis, AM Adkison, J Clin Investig 2002, 109(3): 363-371