Italfarmaco Enters Binding Term Sheet Agreement with Neupharma for an Exclusive Option to Develop and Commercialize Inhaled Teicoplanin

--Inhaled administration of teicoplanin could provide needed treatment improvement for common cystic fibrosis-related lung infection--

--Term sheet lays groundwork for definitive agreement for Italfarmaco to acquire full global rights--

--Agreement pairs Italfarmaco's commercialization and rare disease expertise with Neupharma's innovation in cystic fibrosis--

MILAN, Italy, August 1, 2019 – Italfarmaco Group announced today that Italfarmaco SpA, a member company, has entered into a binding term sheet agreement with Neupharma for an exclusive option to develop and commercialize inhaled teicoplanin. Intravenously administered teicoplanin remains one of the most efficacious antibiotics used to treat cystic fibrosis patients with Methicillin-Resistant Staphylococcus Aureus (MRSA), although the current administration method is inconvenient and results in considerable side effects as well as limited lung penetration. Per the binding term sheet, subject to the execution of the definitive agreement in the second half of 2019, Italfarmaco has obtained an exclusive option agreement for the acquisition of the full global rights to this novel formulation. The term sheet defines that Italfarmaco will provide Neupharma with an upfront payment, development milestones as well as tiered royalties, for a total sum of up to double digits in USD millions, excluding royalties. By in-licensing this innovative, early-stage asset, which is entering Phase 1 clinical testing in Italy and recently received orphan drug designations from both the FDA and EMA, Italfarmaco is strategically expanding its diverse drug development pipeline.

"As a de-risked molecule with safety proven by over 30 years of use, the novel inhaled formulation of teicoplanin, which would deliver the drug directly into the lungs, has the potential to improve the safety, pharmacokinetic and efficacy profile associated with intravenous teicoplanin. As there is currently no defined standard of care for this chronic lung infection, the agreement will allow Italfarmaco to access a new market as well as provide an improved therapeutic option for cystic fibrosis patients suffering from MRSA," commented Antonio Nardi, Director of R&D Portfolio Development at Italfarmaco.

Fabio Borella, President and Co-founder of Neupharma added, "We believe Italfarmaco has the right resources and development expertise that will enable the inhaled formulation of teicoplanin to successfully enter the next stages of clinical development and ideally commercialization. On the whole we value the opportunity to collaborate with this well-established organization."

"This binding term sheet agreement represents another significant step in the expansion and advancement of Italfarmaco's drug development pipeline. As an early-stage rare disease drug candidate, inhaled teicoplanin complements our other later-stage product candidate, Givinostat, which is in Phase 3 clinical testing for the treatment of Duchenne's Muscular Dystrophy and is expected to enter Phase 3 for Polycythemia Vera in the near term. We look forward to completing the full transaction with Neupharma and advancing our vision of bringing innovative and effective new therapies to patients whose needs remain largely unmet," said Dr. Francesco De Santis, President of Italfarmaco.

About Teicoplanin

Teicoplanin is a glycopeptide antibiotic effective against Gram-positive bacterial infections. Orphan drug status for teicoplanin was recently granted by FDA and the European Commission for its therapeutic use in cystic fibrosis. More specifically, the designation is for an inhaled formulation aimed at the treatment of MRSA lung infections in cystic fibrosis patients.

About Cystic Fibrosis
Cystic fibrosis is a chronic and progressive genetically-inherited disease affecting the mucus glands in the respiratory system and the secretory glands in the gastro-intestinal tract. Cystic fibrosis patients are prone to lung infections due to the dramatic decrease of airway mucus clearance that, in turn, results from the presence of thick mucus and reduced ciliary beat frequency.

About MRSA Infection in Cystic Fibrosis
MRSA (Methicillin-Resistant Staphylococcus Aureus) results in a significant increase in pulmonary exacerbations in cystic fibrotic patients, which has been associated with higher morbidity, increased risk of death and lung function decline.

About Italfarmaco SpA
Italfarmaco SpA is a specialty pharmaceutical company of the Italfarmaco Group engaged in the discovery, development, manufacturing and marketing of branded prescription and nonprescription products in more than 60 countries on 5 continents. Italfarmaco's research and development expertise is best demonstrated through its HDAC inhibitor development programs, addressing new therapeutic treatments of specialty and rare diseases. Through both marketed drugs and compounds in development, Italfarmaco is dedicated to serving patients whose needs remain largely unmet.

About Neupharma
Neupharma is a young and modern company focused on innovation aiming at rare diseases, particularly cystic fibrosis. Neupharma is market leader in Italy for the inhaled treatment of Chronic Pseudomonas aeruginosa lung infection, moreover Neupharma distributes in Italy the most advanced medical devices for the inhalation therapy in cooperation with the world leader Pari GmbH.

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