

RECORDATI LICENSES AN INNOVATIVE EPINEPHRINE NASAL SPRAY IN DEVELOPMENT FOR ANAPHYLAXIS PREVENTION

Milan, 21 September, 2020 - Recordati announces the signing of an exclusive license agreement with ARS Pharmaceuticals, a private U.S. company, for the commercialization in the European Union, Iceland, Liechtenstein, Norway, Switzerland, United Kingdom, Russia/CIS, Turkey, Middle East and French-speaking African countries, of ARS-1, an epinephrine nasal spray in late-stage development for the emergency treatment of severe allergic reactions that can lead to anaphylaxis. Under the terms of the agreement an upfront payment is due by Recordati upon signature of the contract and further milestone payments are linked to the regulatory process and commercial performance.

Anaphylaxis is a severe, generalized allergic reaction, characterized by life-threatening breathing or cardiovascular problems and usually associated with skin and mucosal changes. The trigger is exogenous and can be associated with food, insect bites or other allergenic substances. ARS-1 is a liquid formulation of epinephrine associated with Intravail®, an absorption enhancer, contained in a disposable, mono-dose nasal spray device. This innovative formulation represents a new route of administration compared to existing products, increasing patient compliance and fulfilling an unmet medical need. Easy-to-use and needle-free, this solution may eliminate the anxiety and hesitation associated with using an injection device. With use at the first signs of allergic response, it could provide patients and their families the preventive solution to anaphylactic progression.

The marketing authorization application for the 1 mg dose of the product is expected to be filed in the EU by the end of 2020. Furthermore, a dosage strength of 0.65 mg is under development for pediatric patients.

“We are very pleased that ARS Pharmaceuticals has granted Recordati the exclusive license to market its innovative product for the prevention of severe allergic reactions in Europe, Russia, the Middle East and other countries”, stated Andrea Recordati CEO. “This effective innovative formulation of a product for the prevention of life-threatening allergic reactions reinforces our Specialty and Primary care pipeline and provides further diversification to our portfolio in an area where medical needs are not fully satisfied.”

Recordati, established in 1926, is an international pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003828271), with a total staff of more than 4,300, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. Headquartered in Milan, Italy, Recordati has operations throughout the whole of Europe, including Russia, Turkey, North Africa, the United States of America, Canada, Mexico, some South American countries, Japan and Australia. An efficient field force of medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati is a partner of choice for new product licenses for its territories. Recordati is committed to the research and development of new specialties with a focus on treatments for rare diseases. Consolidated revenue for 2019 was € 1,481.8 million, operating income was € 465.3 million and net income was € 368.9 million.

For further information:

Recordati website: www.recordati.com

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