NEWS RELEASE

RECORDATI: MARKET AUTHORIZATION APPLICATION FOR ARS-1 (EPINEPHRINE NASAL SPRAY) ACCEPTED BY EUROPEAN MEDICINES AGENCY

Milan, 30 November 2020 – Recordati announces that the European Medicines Agency (EMA) has accepted a Marketing Authorization Application (MAA) submission by ARS Pharmaceuticals for review of ARS-1 (known as Neffy™ in the USA), an epinephrine nasal spray for the emergency treatment of severe allergic reactions, including anaphylaxis. On 21 September 2020 Recordati announced the signing of an exclusive license agreement with ARS Pharmaceuticals, a private U.S. company, for the commercialization of ARS-1 in 93 countries including those in the European Union.

The MAA submitted to EMA includes data from multiple clinical studies showing that 1 mg of ARS-1 achieves epinephrine exposures that are similar to a 0.3 mg epinephrine IM injection, with rapid absorption (time to peak plasma levels) and clinical response based on surrogate endpoints. Because of its innovative delivery method, ARS-1 has the potential to be as effective as injections in the treatment of severe allergic reactions in a more convenient and less intimidating delivery device. Its needle-free, small and easy-to-use delivery system may help eliminate anxiety and overcome hesitation that is common with injectable epinephrine.

In Europe, based on epidemiology data, about 4% of the general population has experienced an anaphylactic episode. Overall annual net sales of epinephrine auto-injectors in Europe are around € 100 million based on IQVIA prescription data, representing less than 10% of the eligible population. According to the European Anaphylaxis Registry, less than 15% of anaphylaxis episodes are self-treated with an auto-injector. The introduction of ARS-1 in Europe would be a welcome new tool for more patients with severe allergies to administer lifesaving epinephrine safely, quickly and painlessly.

***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.*

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