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NEWS RELEASE

RECORDATI: U.S. FDA APPROVES CYSTADROPS® (Cysteamine Ophthalmic Solution) 0.37%, A NEW PRACTICAL TREATMENT OPTION FOR THE OCULAR MANIFESTATIONS OF CYSTINOSIS

Milan, 25 August 2020 – Recordati today announced the U.S. Food and Drug Administration (FDA) approval of Cystadrops® (cysteamine ophthalmic solution) 0.37%. Cystadrops® is a new, viscous eye drop solution that depletes corneal cystine crystal deposits in people living with cystinosis. Cystadrops® demonstrated a significant reduction in cystine crystal deposits in the cornea of the eye and is the first and only FDA-approved cysteamine drop formulation with four times a day dosing. Cystinosis is a rare genetic condition present from birth that leads to the build-up of cystine crystals throughout the body, causing widespread tissue and organ damage and significant impact on the eyes.

"Cystinosis is a complex disease and early detection and prompt treatment are critical in slowing the development and progression of symptoms. Improvements in the treatment of cystinosis in the last few decades has led to increased life expectancies. Despite these advances, eye manifestations of the disease are a continual struggle for patients," said Clinton Moore, President, Cystinosis Research Network. "Cystinosis patients live with sensitivity to light, eye discomfort, and pain. They often wear sunglasses even when indoors and fight to keep up with daily activities like school and work."

The FDA approval of Cystadrops® was supported by data from two clinical trials, both in which patients received Cystadrops® at a median frequency of four times per day. A Phase 3 open-label, randomized, controlled, two-arm multicenter trial, with 15 patients in the Cystadrops® arm, investigated the reduction in corneal cystine crystal density as assessed by *in vivo* confocal microscopy (IVCM). In the Cystadrops® arm, the trial showed a 40 percent reduction in the IVCM total score across all corneal layers from baseline to 90 days. A Phase 1/2a open-label, adaptive dose-response clinical trial of eight cystinosis patients showed that treatment with Cystadrops® resulted in a 30 percent decrease in IVCM total score that was maintained for the five-year study period.

"People living with cystinosis and their caregivers have to manage multiple medications every day. To reduce their daily burden, Recordati worked to develop a new viscous eye drop formulation for treating corneal cystine crystals," said Andrea Recordati, CEO. "We are pleased to bring Cystadrops® to patients in the U.S., the first FDA-approved cysteamine eye drop formulation that reduces corneal crystals with a practical four times a day dosing."

The safety of Cystadrops® was evaluated in two clinical trials. The most commonly observed adverse reactions were eye pain (stinging), blurred vision, eye irritation (burning), eye redness, discomfort at instillation site (sticky eyes or sticky eyelids), eye itching, watery eyes, and medicine deposit on the eye lashes or around the eyes.

***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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