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HRA Pharma Successfully Completes European Mutual Recognition Procedure for Metopirone

HRA Pharma today announced that Metopirone has been positively assessed through a mutual recognition procedure (MRP) for 15 European countries as a diagnostic test for ACTH insufficiency, in the differential diagnosis of ACTH-dependent Cushing syndrome and for the management of patients with endogenous Cushing's syndrome.

This regulatory milestone was communicated by the reference member state Ireland and will result in subsequent national approvals (granted in Norway, Denmark and Finland, pending in Germany, Italy, Spain, Sweden, , Poland, Belgium, Luxembourg, Portugal, Austria, France, Netherlands and Ireland).

At HRA Pharma, we constantly strive to improve the lives of rare disease patients by enlarging access to our medicines and services worldwide," commented Erin Gainer, CEO of HRA Pharma."The completion of the MRP process represents a significant regulatory milestone for our company and the potential to bring this medicine to a wider population of medical practitioners addressing diagnosis and symptomatic treatment of Cushing's syndrome."

Currently, Metopirone is registered by national procedures in United Kingdom Netherlands, France and Ireland; its indication being different across these countries. Following the Mutual Recognition Procedure, a new Marketing Authorization will be issued for a harmonized indication throughout the 15 countries covered by the approval under MRP.

HRA Pharma has acquired Metopirone from Novartis in 2011 with the objective to make it available to the largest number of patients. Outside the European Union, Metopirone is approved and marketed in Switzerland, Israel, Australia, Japan, USA, New Zealand and Hong Kong. In addition to the 15 European markets included in this MPR, registrations then launches are also currently being planned in the rest of the world where HRA is actively seeking partnerships.

About Metopirone

Metopirone capsules contain the active ingredient metyrapone that works by stopping the natural production of a steroid hormone called cortisol. Cortisol has many important functions on every organ system, but its overproduction leads to a condition called Cushing's syndrome. This is characterized by symptoms such as moon face, accumulation of fat in particular areas of the body and osteoporosis. By decreasing the production of cortisol, metyrapone relieves the symptoms of Cushing's syndrome. It is also used by hospital specialists to aid in the diagnosis of the underlying cause of Cushing's syndrome.

About HRA Pharma

HRA Pharma is a privately-held European pharmaceutical company that designs products, devices and supporting services in niche areas of health and makes them available to doctors and patients worldwide. The company targets therapeutic gaps in the areas of reproductive health and endocrinology, and uses innovative marketing solutions and socially-conscious programs to promote healthy management of drugs and diseases. Headquartered in Paris, France and with subsidiaries across Western Europe, HRA Pharma has built a strong network of R&D, manufacturing, distribution and NGO partners which enables it to satisfy critical patient needs and improve patient health in over 50 countries across the globe. Visit www.hra-pharma.com for more information.

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