PRESS RELEASE

The CNMC initiates disciplinary proceedings against Leadiant Biosciences Spa and Leadiant Biosciences LTD for alleged practices prohibited by the Antitrust Law

- It is investigating a potential abuse of their dominant market position in Spain involving the manufacture and supply of the drug CDCA-Leadiant®.
- This drug is used to treat a metabolic abnormality that causes irreparable damage to the body.
- It is known as an orphan drug, since it lacks an equivalent therapeutic alternative.

Madrid, 22 December 2020 - The CNMC is investigating the companies Leadiant Biosciences SPA and Leadiant Biosciences LTD for practices contrary to Article 2 of Law 15/2007 of 3 July, the Antitrust Law, for allegedly abusing their dominant market position involving the manufacture and supply of the orphan drug CDCA-Leadiant®, used to treat patients with cerebrotendinous xanthomatosis (CTX). (S/0028/20/LEADIANT)

CDCA-Leadiant® contains chenodeoxycholic acid, a substance that is normally produced in the liver from cholesterol and is a component in bile, a liquid that helps digest fats and vitamins in food.

CTX, which is considered a "rare disease", is an inherited metabolic abnormality caused by an error synthesising bile acid in the body. This pathology causes a build-up of fatty acid deposits in various parts of the body, causing irreparable systemic and neurological damage.

In light of the information collected, and of the assistance provided by both the Ministry of Health and the OCU (Consumer Association), the CNMC has decided to initiate disciplinary proceedings against said companies given the reasonable grounds to suspect a violation of Article 2 of Law 15/2007 of 3 July, the Antitrust Law, and Article 102 of the Treaty on the Functioning of the European Union (TFEU).

The initiation of these proceedings does not prejudge the final result of the investigation. A maximum period of 18 months is now open for the CNMC to investigate and settle the case.