

GA_P ADVISES MODERNA ON ITS ESTABLISHMENT IN SPAIN

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Gómez-Acebo & Pombo has advised pharmaceutical company Moderna on its establishment in Spain and on several issues related to the authorisations for the approval of the vaccine at European level



Moderna established a subsidiary in Spain in August 2020 under the name Moderna Biotech Spain SL, which developed the vaccine for COVID-19 known as mRNA-1273. The European Medicines Agency (EMA) assessed the vaccine's compliance to the usual standards for effectiveness, safety and quality before its approval. The vaccine was granted a conditional marketing authorization (CMA) by the European Commission on January 6, allowing vaccination programs using the Moderna vaccine to be rolled out across the European Union. The authorization was based upon the recommendation of the

EMA for use of the COVID-19 Vaccine Moderna for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 18 years of age and older.

Gómez-Acebo & Pombo advised Moderna on the establishment of its subsidiary in Spain, as well as on Spanish matters related to the vaccine approval by EU/EMA with a team made up of Commercial partner Pablo Fernández Cortijo (pictured top left), Regulatory partner and head of the Health Sciences group Irene Fernández-Puyol (pictured top right), Commercial area lawyers Ignacio de la Fuente and Carolina Orri, Labour partner Ignacio del Fraile (pictured bottom left) and associates Lourdes Escassi and Diego Rizo, Tax partner Javier Vinuesa (pictured bottom right) and Tax lawyer Rocío Arias.

Moderna develops advancing messenger RNA (mRNA) science to create a new class of transformative medicines for patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane or secreted proteins that can have a therapeutic or preventive benefit and have the potential to address a broad spectrum of diseases. The company's platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing Moderna the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and autoimmune and inflammatory diseases, independently and with strategic collaborators.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca PLC and Merck & Co., Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense, and BARDA. Moderna has been named a top biopharmaceutical employer by *Science* for the past six years.