EURORDIS urges EU not to follow in footsteps of US with orphan designation of Covid-19 treatments

25 March, Paris – EURORDIS expresses alarm at the US Food and Drug Association's orphan designation for Remdesivir, a medicine previously designated by the FDA for the treatment of the Ebola virus and later for two other SARS and MERS coronaviruses.

> **Yann Le Cam, Chief Executive Officer, EURORDIS-Rare Diseases Europe**, commented, "We understand and support the great urgency to find medicines to treat Covid-19. Indeed, people living with a rare disease are among the most vulnerable during this SARS CoV-2 epidemic. But this is not the way. Gilead's application in the US for orphan designation of Remdesivir, and the FDA's granting of that designation, is in our view a highly questionable abuse of the US Orphan Drug Act. The number of people affected by Covid-19 will soon be above the threshold for classification as a rare disease. We urge the EU to not follow suit and we call on the European Medicines Agency and the European Commission to respect the true spirit of the EU Orphan Medicines Regulation."
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> He continued, "It is the responsibility of EU and national authorities to use channels other than orphan drug regulations to accelerate the availability of treatments for Covid-19. It is clear from the numbers (over 55k cases in the US and already more than 420k cases around the world) that Covid-19 is a global health pandemic and not a rare disease, even if only a minority of patients express mild or severe symptoms. And this number is likely an underestimation due to the high level of people infected who are currently asymptomatic. Gilead should have withdrawn their application for orphan designation as soon as it became clear Covid-19 is a global health pandemic, not a rare disease.
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> The FDA should not provide long-term financial incentives for a treatment which, if it works, could be widely used in the USA. We are disappointed in Gilead, one of the most profitable pharmaceutical companies in the world and whose stock value has increased significantly while the S&P 500 has plunged over 20%, for the actions they have taken."

Orphan designation serves to encourage the development of orphan medicines by creating market conditions in disease areas where there are no treatment or no satisfactory treatments and where there are not sufficient patients to attract investment. **This is not the case for Covid-19. Drug companies are already highly motivated to bring a treatment to market.**

In fact, granting orphan designation is counterproductive as other active substances with a different mechanism of action can also be approved. It will provide a protection for 7 years on the US market against generic competition, hence reducing access to treatments for patients in the US and adding a burden on the US healthcare funding system.

Granting orphan designation to Remdesivir is therefore detrimental to efforts to bring genuine orphan medicines to market and will have a negative impact on rare disease patients' access to other much-needed medicines.

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About EURORDIS-Rare Diseases Europe

EURORDIS-Rare Diseases Europe is a unique, non-profit alliance of over 900 rare disease patient organisations from 72 countries that work together to improve the lives of the 30 million people living with a rare disease in Europe. By connecting patients, families and patient groups, as well as by bringing together all stakeholders and mobilising the rare disease community, EURORDIS strengthens the patient voice and shapes research, policies and patient services.