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AIFA DATA ON ANTIVIRALS AGAINST COVID-19 IN A STUDY ON 'LANCET'

The data from the monitoring conducted by the Italian Medicines Agency on oral antiviral medicines for the treatment of COVID-19 during the pandemic were analysed in a study published on 13 July 2023 in the scientific journal The Lancet Regional Health - Europe.

The publication was received with great interest by the scientific community both for the robustness and volume of data collected through the AIFA Monitoring Registers, and for the statistical methodology applied in the interpretation of the results.

Rigorous investigations conducted on robust data acquired in real life are in fact able to provide valuable clinical evidence on the efficacy and safety of therapies that have obtained an authorisation for emergency use, following the favourable results obtained from randomized clinical trials.

In the editorial accompanying the publication in the journal, the authors highlight that the study "marks an important step towards an evidence-based approach to the treatment of COVID-19 in high-risk patients" and "provides detailed information on the efficacy of treatments that can pave the way for a more personalised approach to future therapeutic strategies".

The study compared mortality in COVID-19 patients treated with molnupiravir or nirmatrelvir plus ritonavir during the Omicron era (between February and April 2022).

«This study was an opportunity to highlight, in the case of antivirals and monoclonal antibodies for COVID-19, the importance of coordination between the Ministry of Health, AIFA and the Regions - underlines **Pierluigi Russo**, Head of the AIFA Monitoring Registers Office - *in which AIFA, thanks to statistical analysis methodologies based on machine learning, has provided a substantial contribution, expanding the opportunities for future research and enriching the information available in decision-making processes».*

The data analysis showed that early treatment with nirmatrelvir plus ritonavir was associated with a significantly reduced risk of all-cause mortality by day 28 compared to molnupiravir, both in the entire study population and in certain subgroups of patients, including those fully vaccinated with the booster dose. In contrast, a higher frequency of adverse events was reported in a subset of patients for whom safety data were available in the nirmatrelvir plus ritonavir cohort.

«This important study highlights how AIFA performs not only regulatory functions, but is also able to make a substantial contribution to the scientific community. - underlines **Giorgio Palù**, President of the Management Board of AIFA - *This is a very significant work not only because it was published in a highly qualified and prestigious journal, but above all because it combines the work of managers and researchers of the Agency and the academic and welfare world of the NHS. Taking advantage of the monitoring registers, it was possible to evaluate what not even the pivotal studies had done: the real-world effectiveness of some medicines. It was therefore possible to evaluate how nirmatrelvir associated with ritonavir and molnupiravir have a differentiated effect».*

In Palù's opinion, these are significant results also for the future of AIFA. *«These are important data for the international community* - adds the President of AIFA – *and, among other things, they bring out the possible role of AIFA in its reform perspective, which is not only regulatory, but also that of promoting constructive*

interaction in the perspective of health protection between research, universities, scientific societies and pharmaceutical companies, also through a new way of approaching the evaluation of medicines not yet authorised by the EMA or FDA, which have data in a still preliminary phase, evaluating the results in clinical practice».

Link to publication::

Real-life comparison of mortality in patients with SARS-CoV-2 infection at risk for clinical progression treated with molnupiravir or nirmatrelvir plus ritonavir during the Omicron era in Italy: a nationwide, cohort study

https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(23)00103-5/fulltext

Link to the editorial:

Shedding new light on COVID-19 therapeutics during the omicron era: a deeper dive into real-world data - The Lancet Regional Health – Europe

https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(23)00113-8/fulltext