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AGENZIA ITALIANA DEL FARMACO

Monoclonal antibodies for COVID-19: AIFA to fund 4 clinical studies

In the context of the Coronavirus epidemiological emergency, the Italian Medicines Agency (AIFA) has issued a call to promote funding of clinical studies to acquire new evidence on the efficacy of monoclonal antibodies in the treatment of COVID- 19 patients at an early stage of illness, not hospitalized, with or without risk factors which may worsen the prognosis.

"AIFA - so Director General **Nicola Magrini** - *has committed to devote a share of research funds to foster independent clinical studies, with an aim to better understand the therapeutic role of this family of drugs and to promote comparative efficacy assessments within the different monoclonal antibodies. The large number of clinical studies proposals we received testifies to the vitality of collaborative research platforms in Italy".*

The research call closed on 15 February; 14 research protocols were submitted which, after being scrutinized to check compliance with the requirements, were all unanimously admitted to the subsequent assessment phases.

For the purposes of funding, projects were privileged which stood out for their feasibility and practical functioning, thus likely to transfer the results into real clinical practice, within a strategic perspective for the National Health Service.
The 4 research protocols selected will access funding promoted by AIFA for an amount of over 2 million euros. The AIFA Board of Directors has approved the outcome of the evaluation and the funding of the studies.

"The projects selected for funding have a high scientific value and the potential to contribute to fully defining the role of monoclonal antibody therapy in preventing progression to the most severe forms of COVID-19. I believe that this initiative promoted by AIFA is consistent with a rigorous clinical research approach to this therapeutic option and should be emphasized as a qualifying element for Italy", so **Franco Locatelli**, Chair of the evaluating board.

Titles and scientific managers of the selected studies

Title	Scientific manager
Adaptive, randomised, placebo-controlled clinical study on the use of monoclonal antibodies in patients with mild-moderate Covid-19 (MANTICO)	TACCONELLI Evelina
A phase III, multicentre, double-blinded, randomised controlled study to compare the efficacy and safety of Casirivimab and Imdevimab or Bamlanivimab and Etesevimab versus placebo in preventing clinical worsening in COVID-19 home patients at high risk of hospitalization	MARIETTA Marco
A phase III randomised, open-label, multicenter study to determine the safety and efficacy of different Monoclonal Antibodies (MoAbs) to SARS-CoV-2 for early treatment of COVID-19 in non-hospitalised adults (MONET Study)	ANTINORI Andrea
AntiCov: a phase III multicentre, controlled, randomised, parallel group clinical study to assess efficacy of monoclonal antibodies versus standard of care for treatment of early-stage COVID-19.	RICHELDI Luca