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AGENZIA ITALIANA DEL FARMACO

USE OF BAMLANIVIMAB MONOCLONAL ANTIBODY IN ITALY FOR THE TREATMENT OF COVID-19: NO FREE OF CHARGE OFFER FROM ELI LILLY, JUST A SALE APPROVAL REQUEST

Recent articles published in national newspapers reported that AIFA would oppose the use in Italy of a monoclonal antibody, Bamlanivimab, produced on the national territory by the pharmaceutical company Eli Lilly, and that the company would have offered the product free of charge without receiving any feedback. These statements are misleading and unfounded.

Therefore, the following is clarified:

1. AIFA has never received any proposal for a free-of-charge sale, compassionate use or supply within a clinical trial setting of the Bamlanivimab monoclonal antibody from Eli Lilly.
2. At the beginning of October, the company expressed a general willingness to cooperate with the authorities in order to identify ways of using the medicinal product in Italy, without ever offering free batches. This followed despite an explicit request made by AIFA representatives at a meeting held on 29 October, with the participation of the Agency's Technical-Scientific Committee, that was specifically convened to show AIFA's willingness to consider any sustainable possibility of access to new treatments.
3. On 20 November, Eli Lilly submitted to AIFA an offer for the purchase of the medicinal product by the National Health Service (NHS), and on 25 November forwarded a draft contract to the office of the commissioner for the Covid-19 emergency.
4. Monoclonal antibodies require a European approval procedure. However Eli Lilly proposed that the medicinal product be approved in derogation from such procedure. EMA expressed a very prudent opinion on the possibility of approving Bamlanivimab on the basis of a Phase 2 study showing moderate benefits, and requested additional supporting evidence.
5. The request to authorise the medicinal product pursuant to a special provision of the pharmaceutical legislation (article 5, paragraph 2, of Directive 83/2001, as transposed in Italy by Legislative Decree 219/2006) is not acceptable given the current pandemic in which all EU Member States are confronted with the same problem and a common European effort is needed to overcome it, as shown by the recent EMA authorisation of COVID-19 vaccines. For this reason, AIFA expressly suggested the company to submit an authorisation application to EMA.

It should be noted that the emergency use authorisation granted by the FDA in the US provides for a lower level of scientific evidence than the (full or conditional) approval recommended by EMA.

AIFA is committed to ensuring clear and transparent access to all medicines of proven efficacy and safety, based on the best scientific evidence, in order to protect citizens and patients as well as to safeguard the sustainability of the National Health Service.