The monoclonal antibody made in Italy that we do not use.

Produced in Latina, it could treat 10 thousand sick people (for free). The bureaucrats leave it to the USThanks to the therapy used by Trump, 10,000 of our patients could have been cured. But the green light for experimentation is still stalled. Clementi:

"We have 'bullets' that can save thousands of patients, but we decide not to shoot them"By Thomas MackinsonDecember 17, 2020CommentsTen thousand Italians could recover immediately, like so many Donald Trump. Instead, while waiting for a vaccine, Italy is facing the third wave of Covid without therapies based on monoclonal antibodies, those that neutralize the virus in three days avoiding hospitalization.

In fact, vans loaded with these drugs come out of a Latina plant, but they are destined to save American patients, not Italians. To which, moreover, they had already been offered free of charge two months ago. It is the paradox of a story that has heavy health, political and ethical implications. "We have specific 'bullets' against the virus.

They can save thousands of patients, avoid hospitalizations and infections, but we decide not to shoot them. It cannot be explained ", Massimo Clementi, virologist at San Raffaele in Milan, has been repeating for days.He says that colleagues in the United States have been administering neutralizing antibodies as therapy and prophylaxis for Covid patients for several weeks.

The same cure that saved Donald Trump's life in a few days, despite his age and overweight: "After 2-3 days they recover with no apparent side effects." All this for around 1000 euros for a complete treatment, compared to 850 euros for a daily hospitalization.The United States bought 950,000 doses, followed by Canada and - yesterday's news - Germany.

Not Italy, where they are produced.

Our country has invested in a promising monoclonal made in Italy but available only in 4-6 months. Very pragmatic scientists are wondering why, in the meantime, drugs that already prove effective elsewhere are not used: since October - it turns out now - Italy had been given the opportunity to use these antibodies through a so-called "clinical trial", in which 10 thousand doses of the drug would be offered free of charge.

A hand from the sky mysteriously rejected as the country plunged into the second wave.The drug - bamlanivimab or Cov555 - was developed by the American multinational Eli Lilly. Its effectiveness in reducing viral load, symptoms and risk of hospitalization is demonstrated by a randomized Phase 2 study (phase 3 is ongoing) conducted in the USA.

The findings were featured in the prestigious New England Journal of Medicine. From the Sesto Fiorentino headquarters they explain that the antibody was put into production even before the trial was finished so that it would be available on a global scale as soon as possible.Since November 9, when the FDA cleared it for emergency use, the United States has purchased nearly one million doses.

In Europe, the green light is expected from the EMA, which does not authorize medicines under development. However, a European directive of 2001 allows individual EU countries to proceed with the purchase and Germany yesterday completed the procedure to authorize it.

Soon it will be Hungary's turn. It's Italy? Wait up. Having its European heart at the gates of Florence, after completing the study, the Indianapolis company made contact with the national health and political authorities, including Italian ones. On 29 October meeting with AIFA: connected, among others, Gianni Rezza for the Ministry of Health;

Giuseppe Ippolito of the Cts and director of the Spallanzani of Rome; Professor Guido Silvestri, a virologist at Emory University in Atlanta who had favored contact with Eli Lilly. On the table, the possibility of starting the experimentation in Italy with at least 10 thousand free doses of the drug which in the USA has been shown to reduce the risk of hospitalization from 72 to 90%

. In that context, it is also made clear that it would not have been a favor to the multinational, on the contrary: once the FDA had authorized it, requests from other countries would have left. The opportunity, to be seized on the fly, falls on deaf ears, perhaps due to a strict adherence to the AIFA and EMA rules which, however, have not stopped the rigorous Germany.

Another hypothesis: the offer was dropped due to a choice already made upstream. Since March, the Government has invested 380 million on monoclonals for an all-Italian project headed by the Toscana Life Sciences (TLS) foundation, a non-profit organization in Siena, in collaboration with Spallanzani and directed by the luminary Rino Rappuoli.

The clinical trial has yet to start and the production, barring hitches, will start only in spring 2021. As far as the Fact is concerned, the operation with Eli Lilly, which two months ago would have allowed thousands of people to be saved, would not have gone through. for the critical attitude towards these antibodies of the director of Spallanzani who will work on the Sienese project.

“I don't know why it went like this, you have to ask AIFA”, director Giuseppe Ippolito cuts short, denying a conflict of interest: “I don't prescribe drugs, I only deal with science”.When the FDA authorizes the drug, the multinational can no longer offer the free trial but must stick to the parent company's price. Ironically, with the zero-cost option vanished, Italy expresses an official expression of interest in the purchase.

The negotiations take place on November 16 in the presence of Arcuri, the Aifa Magrini DG and the Minister of Health Speranza. There is talk of price and doses but the negotiation stops there and does not go on. Not even when the mayor of Florence returns to office.

Dario Nardella announces to the newspapers that he has spoken with the leaders of Eli Lilly and that "if there is the approval of the EU Commission, the distribution of the drug based on monoclonal antibodies could begin after Christmas not only in France, Spain and the United Kingdom but Also in Italy".

Christmas is upon us and in Italy there is no trace of antibody drugs nor is there any news of pressure from AIFA to solicit the European agency of the same name. As if the therapeutic option for patients battling the virus, already available elsewhere, is of no interest.AIFA and the Arcuri structure - heard by the Fact - reiterate: as long as there is no EMA authorization, we cannot go on.

One can even die of too much caution, scientists reply.

"I would have accelerated", says the consultant of Minister Walter Ricciardi, present at the meeting a month ago: "With so many deaths and hospitalized, it is an ethical and moral imperative to evaluate all available therapies soon." The virologist Silvestri, who had pushed so much: "I don't understand what is blocking the introduction of Lilly and / or Regeneron antibodies, which we use here in the States with very encouraging results".

Last night the critical voice of the immunologist of the University of Padua Antonella Viola was added: "This delay is surprising, what are we waiting for?".For Professor Clementi, we are at the paradox. “It is important to find the best drug possible, but we cannot a priori discard a therapeutic possibility that elsewhere saves people.

A vial costs a little more than a day of hospitalization and every resource you save can be used for something else. Keeping a weapon that proves decisive in its sheath is incomprehensible. Hence, my solicitation to AIFA ".