Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Bebtelovimab: considerations for global access to treatments during a rapidly evolving pandemic

Given the activity of bebtelovimab against current global circulating SARS-CoV-2 variants, Hentzien and colleagues[1] raise several questions as to why bebtelovimab is unavailable outside the USA.

Lilly agrees that bebtelovimab should be available outside the USA. We remain open to communication with global health authorities, including presenting the data package upon request;[2] however, due to local regulations, health authorities might not have an emergency use pathway or might decide that the current data package for bebtelovimab is insufficient for authorisation.

The COVID-19 pandemic prompted immediate adaptive innovations by drug developers and regulatory agencies to quickly provide life-saving therapeutics and vaccines. Lilly's COVID-19 monoclonal antibody programme adapted to pandemic requirements during the development of bamlanivimab alone and in combination with etesevimab, positively influencing the development of bebtelovimab and its emergency use authorisation by the US Food and Drug Administration (FDA). As summarized by Dougan and colleagues,[3] the successful development of bebtelovimab was achieved with proactive studies, continuous virus surveillance, and streamlined clinical design. For instance, live virus neutralisation assays that confirmed potent neutralisation against circulating SARS-CoV-2 variants correlated with in vivo efficacy and allowed for efficient transition to in-human phase 1 trials.[4,5] Additionally, US regulatory acceptance of changes in viral load and sustained symptom resolution as surrogate markers of COVID-19 improvement, as opposed to severe and infrequent clinical outcome measures (eg, admission to hospital and death), allowed emergency use authorisation with available phase 2 data.

Emergency use authorisation of bebtelovimab was also achieved through adaptation and proactive communication from the FDA with sponsor companies, to ensure alignment on clinical trial data and packages intended for emergency use authorisation submissions. Thus, when the omicron (B.1.1.529) variant became the predominant variant and authorised antibody treatments were no longer effective, the available data supporting bebtelovimab (non-clinical live virus neutralisation data and phase 1 and 2 results) were deemed sufficient by the FDA for emergency use authorisation of the drug in the USA for the treatment of mild to moderate COVID-19 in certain high-risk patients for whom alternative COVID-19 treatment options approved or authorised by the FDA are not accessible or clinically appropriate. Additionally, Lilly is currently fulfilling conditions of the emergency use authorisation that require a study to further evaluate bebtelovimab,[5] including conducting a trial to evaluate the pharmacokinetics and safety of bebtelovimab in paediatric patients.

This modified regulatory approach which met the US requirements for emergency use during a health emergency, or regulatory mutual recognition, could serve as a global model to accelerate authorisation of next-generation vaccines and therapeutics within the current and future pandemics to help patients worldwide.

RMN, CD, and HU are salaried employees and stockholders of Eli Lilly and Company.

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Viral replication and infectivity of monkeypox through semen

With great interest, we read the findings presented by Daniele Lapa and colleagues,[1] showing the successful isolation of monkeypox viral DNA from the seminal fluid of an infected patient. The authors suggested that monkeypox might have a genital reservoir because of the persistent viral shedding in seminal samples, even at low viral copies. These findings could indicate that the current monkeypox outbreak predominantly spreads through sexual transmission, especially after the various reports that estimated that most monkeypox cases were reported among individuals who identify as men who have sex with men. Understanding the mode of transmission could allow for the development of proper interventional approaches to reduce the intensity of the current outbreak.

Monkeypox DNA presence in the seminal fluids might be due to local genital replication or passive diffusion

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