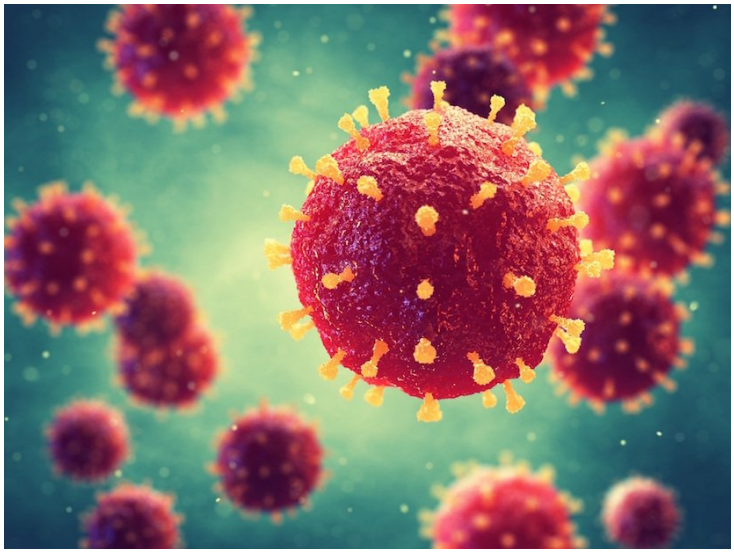
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Current therapies for new SARS-CoV-2 variants require adjustments: GlobalData

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The FDA revoked the EUA for bamlanivimab as monotherapy



The emergence of new SARS-CoV-2 variants have been detected in over 40 countries and are disrupting drug development worldwide. The prevalence of these more transmissible strains is growing fast and may require adjustments to current therapies to ensure they retain clinical efficacy, says GlobalData.

Nancy Jaser, Pharma Analyst, GlobalData, comments, “More data is now required for all potential and current COVID-19 therapies given the rapid spread of variant strains. While monoclonal antibody treatments will likely be more scrutinised due to their specific targets, vaccine development also needs to be re-assessed to determine efficacy and durability across the various platforms.”

“Eli Lilly’s mAbs, bamlanivimab and etesevimab, will likely stumble in attempts to gain full FDA approval given the antiviral resistance observed against B.1.351, P.1., and the New York variant, B.1.526. However, optimism remains for its mAb combination to prove effective against the UK B.1.1.7 variant, which is currently the most dominant in the US with 7,500 reported cases.”

Regeneron and Eli Lilly were both granted an EUA for mAbs against COVID-19. According to recent data, Lilly's single mAb (bamlanivimab) is not effective against most variants, while the combo (bamlanivimab/etesevimab) is slightly better with potency detected against B.1.1.7. The FDA revoked the EUA for bamlanivimab as monotherapy. However, Regeneron's mAb combo (casirivimab/imdevimab) has been proven to be the most effective against the emerging variants.

Data shows that the South African variant can escape from most mAb therapies. Experts believe this B.1.351 variant is more heavily mutated than the UK B.1.1.7 strain and will be the most difficult to contain.

Top-line Phase III trial data for Regeneron’s antibody cocktail REGEN-COV (casirivimab and imdevimab) was positive, meeting its primary endpoint by reducing the risk of hospitalisation or death by 70 per cent compared to placebo. REGEN-COV also met all secondary endpoints which included reducing the duration of symptoms by four days. With an EUA already granted in the US, Regeneron plans to submit a BLA including this most recent Phase III data. Further, FDA updates indicate that REGEN-COV is the only mAb therapy that has retained potency against these emerging strains.