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Limits of Monoclonal Antibody Treatment in Pregnant Women Complicated with COVID-19 Due to The Omicron Variant

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Dear Editor:

Administration of neutralizing monoclonal antibodies (mAbs) of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been reported to reduce disease progression in those at high risk of disease progression [1]. In November 2021, the coronavirus disease 2019 (COVID-19) Treatment Guidelines Panel (Panel) recommended the use anti-SARS-CoV mAbs products, such as bamlanivimab plus etesevimab (Eli Lilly and Company, Indianapolis, IN, USA), casirivimab plus imdevimab (REGEN-COV, Regeneration Pharmaceuticals, Tarry Town, NY, USA) or sortrovimab (GlaxoSmithKline plc, Brentford, UK) to treat non-hospitalized patients with mild to moderate COVID-19 who are at high risk of clinical progression and pregnant patients [2]. The Korean Society of Infectious Diseases released similar guideline [3], and the American College of Obstetricians and Gynecologists and the Society of Maternal-Fetal Medicine also support it [4]. We provided information regarding the administration of regdanvimab (Celltrion, Incheon, Korea), the only available mAb in Korea, to 22 pregnant women with mild symptoms of COVID-19 between December 2021 and January 2022 who met the following criteria: positive result based on nasopharyngeal polymerase chain reaction testing, unvaccinated or incompletely vaccinated status, onset of symptoms within 7 days, and SpO_2 >94% in room air with no requirement for oxygen supplementation. Three patients consented to administration of regdanvimab (**Table 1**). Their maternal age ranged from 33 - 34 years; their gestational age at the time of the treatment ranged from 14 to 27 weeks. All patients received regdanvimab without any immediate acute complications and continued their pregnancies. Although it was too small number of patients to conclude whether mAb therapy is effective treatment in pregnant women, we could find there was no acute complication in our study group. Therefore, we planned to administer mAb to pregnant women with mild COVID-19. However, in January 2022, the U.S Food and Drug Administration (FDA) revised the authorizations for two monoclonal antibody treatments

Table 1. Patient characteristics and outcomes

Patient	Age (yr)	BMI (kg/m²)	Co-morbidity	Gestational age at treatment (wk+d)	COVID-19 severity at treatment	COVID-19 progression or additional care required	Pregnancy outcomes
1	33	22.8	No	17 + 0	Mild	No	Currently 25 weeks pregnant
2	34	21.7	No	26 + 6	Mild	No	Currently 32 weeks pregnant
3	34	22.1	No	14 + 2	Mild	No	Currently 18 weeks pregnant

BMI, body mass index; COVID-19, coronavirus disease 2019.

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Ethics statement
This study was approved by the Institutional Review Board of Kyungpook National University Hospital (IRB file No.: KNUCH-2019-02-044) and written informed consent was obtained from participants.

Conflict of Interest
No conflict of interest.

Author Contributions
Conceptualization: WJS. Data curation: HHC, SK, HMK, MJK. Formal analysis: HHC. Investigation: HHC, WJS. Methodology: HHC, SK Project administration: HHC, WJS. Resources: HHC, SK, HMK, MJK. Software: HHC. Supervision: WJS. Validation: HHC, SK. Visualization: SK. Writing - original draft: HHC. Writing - review & editing: HHC, WJS.

— bamlanivimab plus etesevimab and REGEN-COV and limited their use to only when the patient is likely to get infected or exposed to a variant that is susceptible to these treatments [5]. Because the omicron variant of SARS-CoV 2 is estimated to account for more than 99% of cases in the United States from January 2022, the FDA did not authorize the use of these mAbs at this time. In Korea, the first cases of omicron variant (a couple) were reported on December 1, 2021 [6], and it became dominant variant on third week of January, 2022 [7]. The Korea Centers for Disease Control and Prevention Agency is also concerned with the reduced activity against the omicron variant of regdanvimab and recommends the caution of mAb administration in omicron dominant situations [8]. Because the variant type in our study group was not confirmed, we could not report whether mAb therapy is effective treatment in pregnant women during the omicron variant dominant era. We are writing this letter to share our experience about the administration of mAb to pregnant women, information regarding the administration of mAbs which is changing with emerging a new variant.

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