Infect Dis Ther
https://doi.org/10.1007/s40121-021-00564-x

LETTER

A Response to: Letter to the Editor Regarding Management of Adult Patients with COVID-19 Outside Intensive Care Units: Guidelines from the Italian Society of Anti-Infective Therapy (SITA) and the Italian Society of Pulmonology (SIP)

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Received: October 15, 2021 / Accepted: November 9, 2021

Keywords: COVID-19; mAbs; Monoclonal antibodies; SARS-CoV-2; Casirivimab; Imdevimab; Guidelines

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Dear Editor,

We thank Manciulli and colleagues for their comment on the recently released guidelines from the Italian Society of Anti-Infective

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Published online: 10 December 2021

Therapy (SITA) and the Italian Society of Pulmonology (SIP) on the clinical management of adult patients with coronavirus disease 2019 (COVID-19) outside intensive care units [1, 2]. In their comment, Manciulli and colleagues highlight that, while in the guidelines there is a recommendation against the use of neutralizing monoclonal antibodies in inpatients with COVID-19 (pending results of ongoing trials), the Italian Medicine Agency (AIFA) has recently allowed the use of casirivimab/imdevimab at high dosage in hospitalized seronegative patients with COVID-19 [3]. This apparent discrepancy is mostly related to the fact that the randomized trial (currently available as a non-peer-reviewed pre-print manuscript [4]) supporting the AIFA decision became available only very recently, after the last literature update dictating guidelines development. The possibility of novel evidence becoming available after the release of the guidelines was not unexpected. Indeed, a novel rigorous literature search supporting a predefined update of the current guidelines is about to start in November 2021, as stated in the guideline methods [1].

Nonetheless, it is certainly true that novel evidence cannot be ignored. For this reason, pending the predefined update of the current guidelines, we invite Italian physicians to follow the most recent regulatory document, i.e., the current AIFA recommendations on the use of neutralizing monoclonal antibodies in non-hospitalized and hospitalized patients with COVID-19. However, an important point of caution is that neither the certainty of evidence nor the strength for this recommendation can be reliably defined without the proper methodology. Indeed, the formulation of the final, updated SITA and SIP recommendations on the use of neutralizing monoclonal antibodies (both in inpatients and in outpatients and both for intravenous and for other available formulations) will be provided after following the same rigorous systematic steps that were taken during the preparation of the first released document. This is necessary to guarantee the

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required high-quality standards for guideline development.

ACKNOWLEDGEMENTS

Funding. No funding or sponsorship was received for this study or publication of this article.

Authorship. All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

Author Contributions. Matteo Bassetti: project chair for SITA, project concept, voting panel member, revision of final manuscript and supplementary material. Francesco Blasi: project chair for SIP, project concept, voting panel member, revision of final manuscript and supplementary material. Daniele Roberto Giacobbe: project coordinator, methodology and systematic reviews, assessment of evidence with the GRADE system, drafting of recommendations, drafting of final manuscript and supplementary material, supervision of voting process. Pierluigi Viale, Malgorzata Mikulska, Nicola Petrosillo, Andrea Gori, Carlo Tascini, Francesco Giuseppe De Rosa, Pierachille Santus, Fabiano Di Marco, Stefano Centanni, Carlo Vancheri, Angelo Gratarola, Federico Pea: voting panel members, revision of final manuscript and supplementary material. Antonio Vena, Guido Granata, Silvia Corcione, Emanuela Sozio, Nadia Castaldo, Andrea Lombardi, Andrea Gramegna, Dejan Radovanovic, Elena Tagliabue: search strings development, conduction of systematic reviews, drafting of recommendations, revision of final manuscript and supplementary material. Alessio Signori: development and supervision of methodology together with the project coordinator, revision of final manuscript and supplementary material. Alberto Enrico Maraolo: development and supervision of methodology together with the project coordinator, assessment of evidence with the GRADE system, search strings development, revision of final manuscript and supplementary material. Paolo Bruzzi: development and supervision of methodology together with the project coordinator, assessment of evidence with the GRADE system, revision of final manuscript and supplementary material.

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Disclosure. Outside the submitted work, Daniele Roberto Giacobbe reports an unconditional grant from Correvio Italia and a grant for his institution by Pfizer Inc. Outside the submitted work, Matteo Bassetti has received funding for scientific advisory boards, travel and speaker honoraria from Angelini, Astellas, Bayer, BioMérieux, Cidara, Cipla, Gilead, Menarini, MSD, Pfizer, Shionogi, Tetraphase, Nabriva. Outside the submitted work, Francesco Blasi reports grants and personal fees from AstraZeneca, grants from Bayer, grants and personal fees from Chiesi, grants and personal fees from GlaxoSmithKline, personal fees from Grifols, personal fees from Guidotti, personal fees from Insmed, grants and personal fees from Menarini, personal fees from Novartis, grants and personal fees from Pfizer, personal fees from Zambon, and personal fees from Vertex. Outside the submitted work, Emanuela Barisione reports personal fees from Boehringer Ingelheim, personal fees from Chiesi, and personal fees from GlaxoSmithKline. Outside the submitted work, Federico Pea participated in speaker bureau for Angelini, Basilea Pharmaceutica, Gilead, Hikma, Merck Sharp & Dohme, Nordic Pharma, Pfzer and Sanofi Aventis, and in advisory board for Angelini, Basilea Pharmaceutica, Correvio, Gilead, Hikma, Merck Sharp

& Dohme, Nordic Pharma, Novartis, Pfizer, Shionogi and Thermo-Fisher. Outside the submitted work, Nicola Petrosillo reports personal fees from MSD, personal fees from Pfizer, personal fees from Johnson & Johnson, personal fees from Shionogi, personal fees from Takeda, and personal fees from Becton & Dickinson. Outside the submitted work, Pierachille Santus reports personal fees from Gilead. Paolo Bruzzi, Stefano Centanni, Nadia Castaldo, Silvia Corcione, Francesco Giuseppe De Rosa, Fabiano Di Marco, Andrea Gori, Andrea Gramegna, Guido Granata, Angelo Gratarola, Alberto Enrico Maraolo, Malgorzata Mikulska, Andrea Lombardi, Dejan Radovanovic, Alessio Signori, Emanuela Sozio, Elena Tagliabue, Carlo Tascini, Carlo Vancheri, Antonio Vena, and Pierluigi Viale have nothing to disclose.

Compliance with Ethics Guidelines. This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

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