# SARS-CoV-2 Monoclonal Antibody Workshop

Presented by Marco Cavaleri on 15 Dec 2022
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# EU regulatory approaches

- **All EU-approved monoclonal antibodies** have a **full approval** and no EUA
  - In the EU there is no EUA in the regulatory toolbox
  - Article 18 or Article 5(3) recommendations are intended to support the emergency use of an unauthorised medicinal product at the national level (EU member states).
- **Conditional marketing authorisation might be justified only in specific cases,** e.g., manufacturing aspects in the context of a declared emergency
- Approval of monoclonal antibodies in the EU has been based on RCTs demonstrating clinical efficacy against previously circulating variants.
- As virus evolves in an unpredictable way, **continuous formal re-assessment of benefit risk not deemed necessary**
- In line with rules for SmPCs**, avoidance** of **any restrictions of indication**, unless considered necessary

# Topics of Particular Interest

- Similar to vaccines, can **an immunobridging approach** be considered suitable to infer efficacy of new monoclonal antibodies

- Factors to be considered if the new monoclonal antibodies product is **not based on an established platform**

- Suitability in the context of **prophylaxis vs treatment** and factors to additionally consider in the different settings

# Topics of Particular Interest (2)

- Perspective on the advantages and disadvantages of **comparing the activity of a new product** against **current circulating variants** to the **activity of an approved product against variants** that were in **circulation during the clinical trial** that demonstrated efficacy of the approved product.

- Perspectives on how the difficulties to **justify a dose increase/adjustment** of currently EU-approved monoclonal antibody therapies in order **to tackle new variants** could be approached.

EUROPEAN MEDICINES AGENCY

# Thank you for your participation

# Any questions?

## Further information

[Insert relevant information sources or contact details as applicable.]

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