A microscopic view of several COVID-19 virus particles. The particles are spherical and covered in numerous small, orange, spike-like protrusions. They are set against a dark background with a bokeh effect of out-of-focus light spots in shades of orange and yellow.

**HHS/ASPR / Project ECHO
COVID-19 Clinical Rounds
March 30, 2021**

Monoclonal Antibodies for COVID-19: Mayo Clinic Process and Outcomes

Raymund R. Razonable, M.D., Professor of Medicine, Mayo Clinic

MATRx Team

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Disclosures

- Research grant: all research grant funds to institution
 - Roche (tocilizumab)
 - Regeneron (sarilumab, spike monoclonal antibody trials)
 - Gilead (remdesivir)

- DSMB: Novartis



Monoclonal Antibodies Therapies for COVID-19

FDA EUA: Mild to moderate COVID-19, within 10 days of symptoms onset, in patients at risk of progressing to severe COVID-19 and/or hospitalization

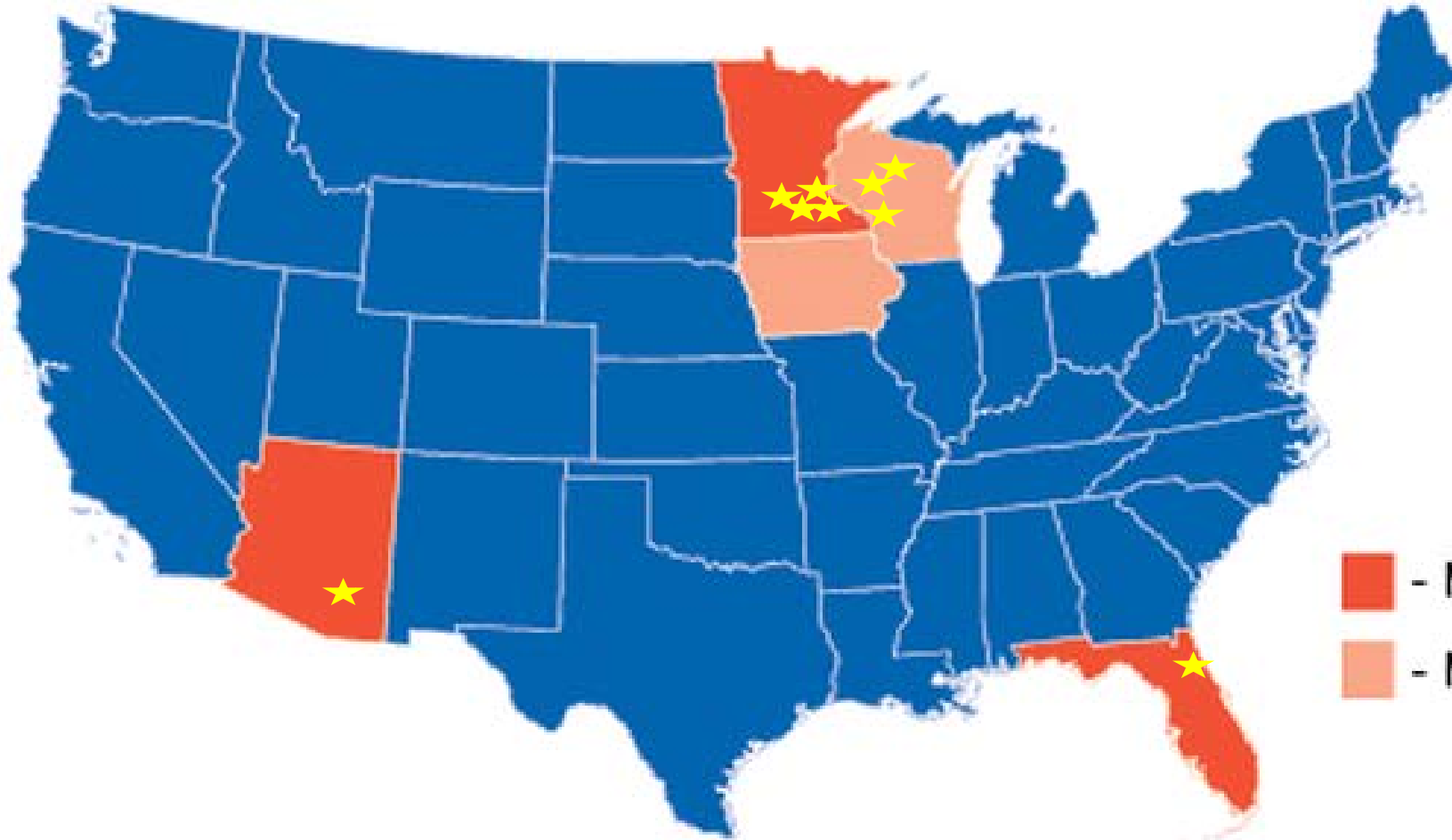
Bamlanivimab (November 9, 2020)

Casirivimab + imdevimab (November 21, 2020)

Bamlanivimab + etesevimab (February 9, 2021)

Mayo Clinic Outpatient Covid-19 Therapy Centers



Rochester. Cannon Falls. Albert Lea. Mankato. Eau Claire. Barron.



La Crosse.

Phoenix.

Jacksonville.

-  - Main campus sites
-  - Mayo Clinic Health System sites

Real-World Experience of Spike Monoclonal Antibodies

Challenges: Personnel

MATRx - Monoclonal Antibody Rx Team

- Multidisciplinary team of clinicians (Infectious Diseases, Internal Medicine, Family Medicine, Pediatrics), CFCT, PCCT, ITC, IPAC, nurses, pharmacists, desk operations, legal and compliance, facilities, engineering, informatics and EHR specialists, medical ethics, administrative operations, administration, many more!






Real-World Experience of Spike Monoclonal Antibodies

Challenges → Patient Education and Consenting

- Patient concerns → patient education video and materials
 - Unaware of the monoclonal antibody therapies
 - Minimal symptoms (did not feel the need for therapy until they get clinically worse)
 - Hesitancy due to investigational nature (EUA)
- Equity, health disparities, underserved populations

BRIEF REPORT

A mobile unit overcomes the challenges to monoclonal antibody infusion for COVID-19 in skilled care facilities

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All COVID +

- Patients with laboratory-confirmed SARS-CoV-2 infection is pulled on daily report
- Referral of Non-Mayo Clinic patients and Mayo Clinic patients with outside tests (eConsult CFCT)
- Referrals reviewed, abstracted and added into Electronic Health Records (copy of positive test)

MASS Score >1

- Determination of clinical eligibility and drug allocation
- Monoclonal Antibody Screening Score (MASS) was developed based on internal outcomes data and eligibility criteria set in the FDA emergency use authorization and state guidance

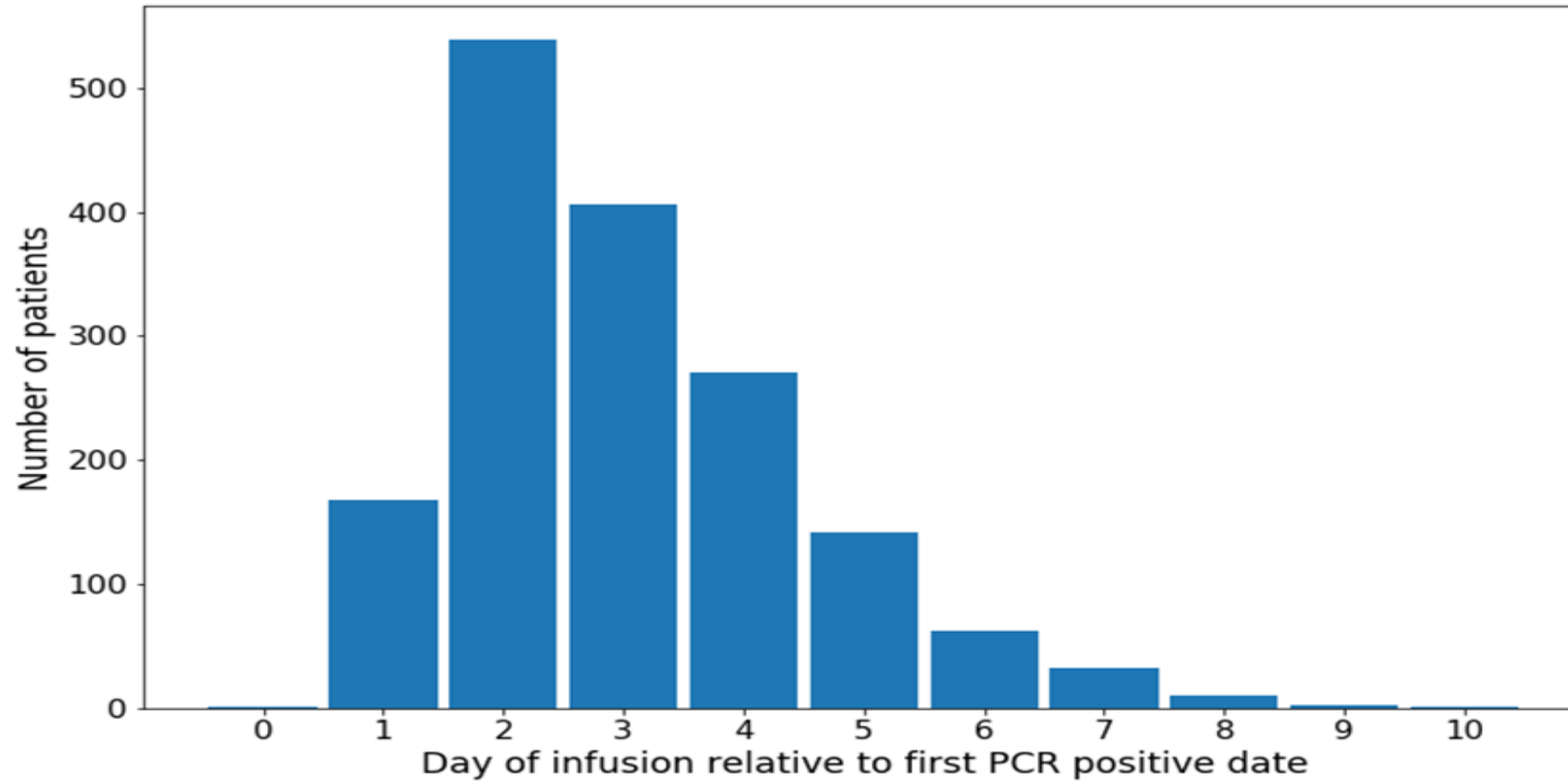
Manual Review

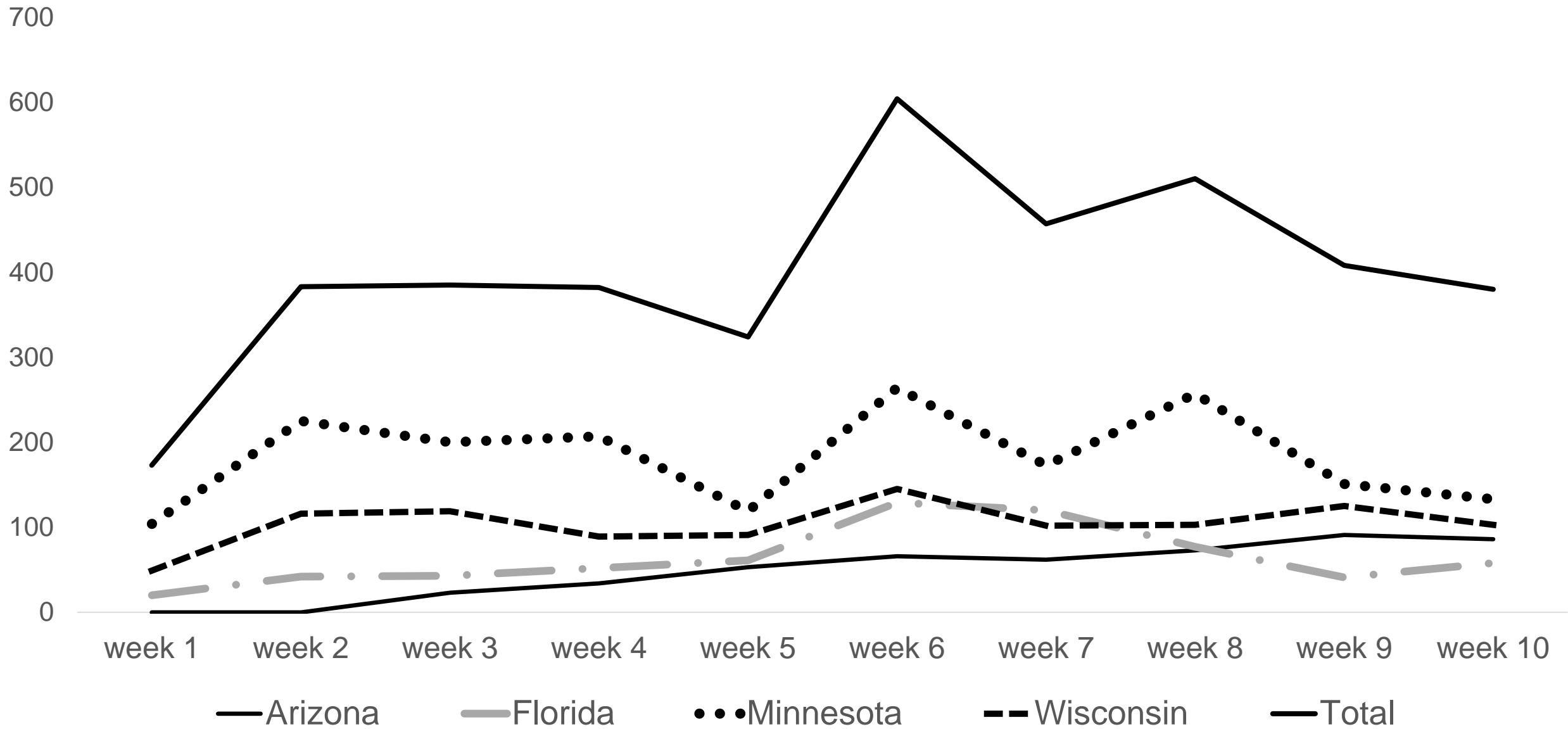
- Eligible patients screened to ensure they reside in respective regions
- Verification of comorbidities by manual review of Electronic Health Record
- Verification of eligibility based on onset of symptoms, severity of illness and date of testing

Patient Education and Consenting

- Patients contacted for education of monoclonal antibodies and obtain consent for infusion
- Consenting patients scheduled for infusion as soon as possible
- Undecided and non-consenting patients are provided 48 hours of time to reconsider decision (patient education video and other materials, partnership with primary providers)

Infusion date relative to PCR date





Program Milestones

- November 9 in Rochester and the Midwest
- November 19 – first monoclonal antibody infusion
 - 1000 patients (Midwest) on 12/25/2020
 - 1700 patients (enterprise) by end of 2020
 - 2000 patients (enterprise) by 01/04/2021
 - 2000 patients (Midwest) by 01/15/2021
 - 2950 patients (enterprise) by 01/19/2021
 - 4600 patients (enterprise) by 03/19/2021
- Nursing homes, homeless and underserved populations, dialysis units

FULL LENGTH ARTICLE | [ARTICLES IN PRESS](#)



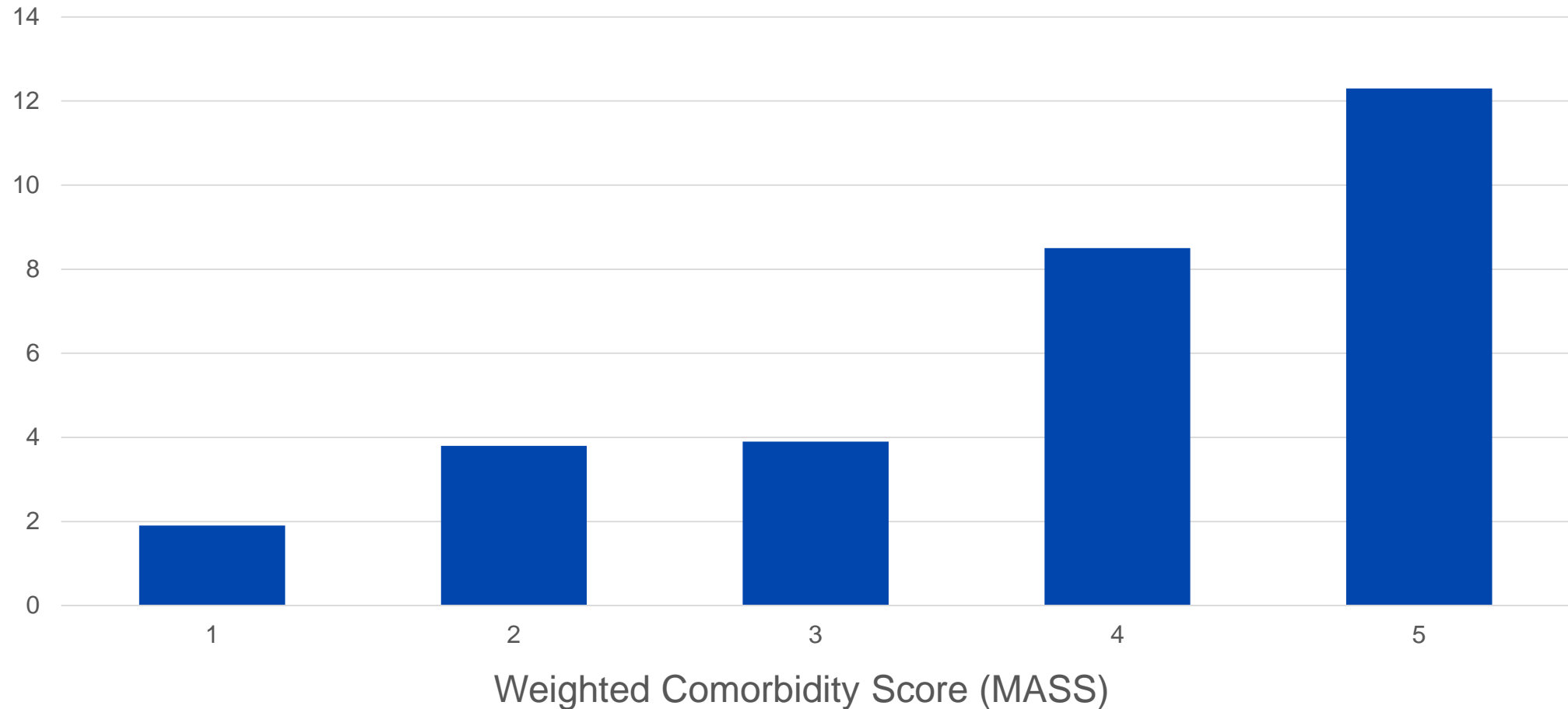
PDF [734]

A Framework for Outpatient Infusion of Anti-Spike Monoclonal Antibodies to High-Risk Patients with Mild to Moderate Coronavirus Disease-19: The Mayo Clinic Model

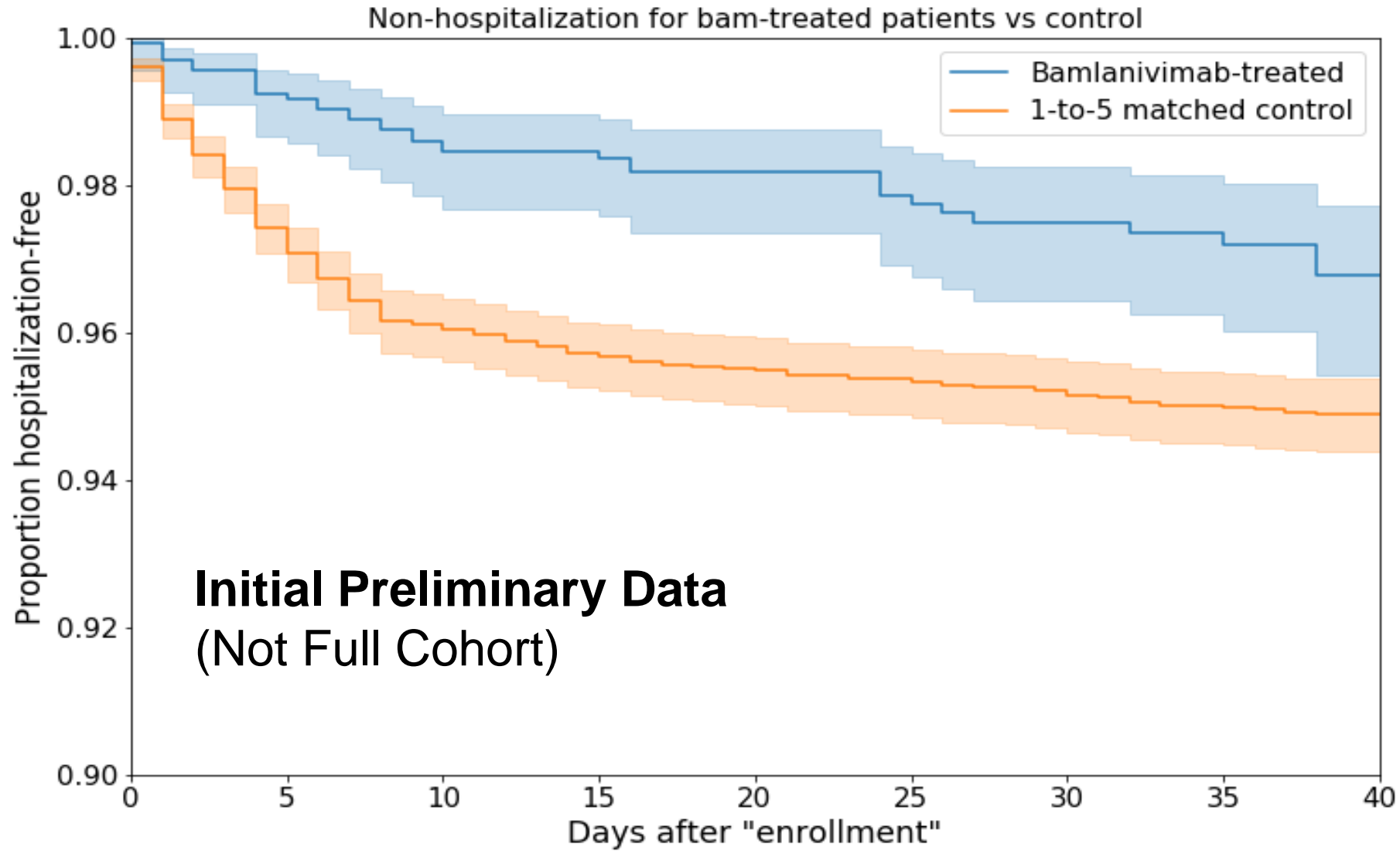
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Published: March 09, 2021 • DOI: <https://doi.org/10.1016/j.mayocp.2021.03.010>

Hospitalization Rates per Monoclonal Antibody Selection Score in Patients who Declined Monoclonal Antibody



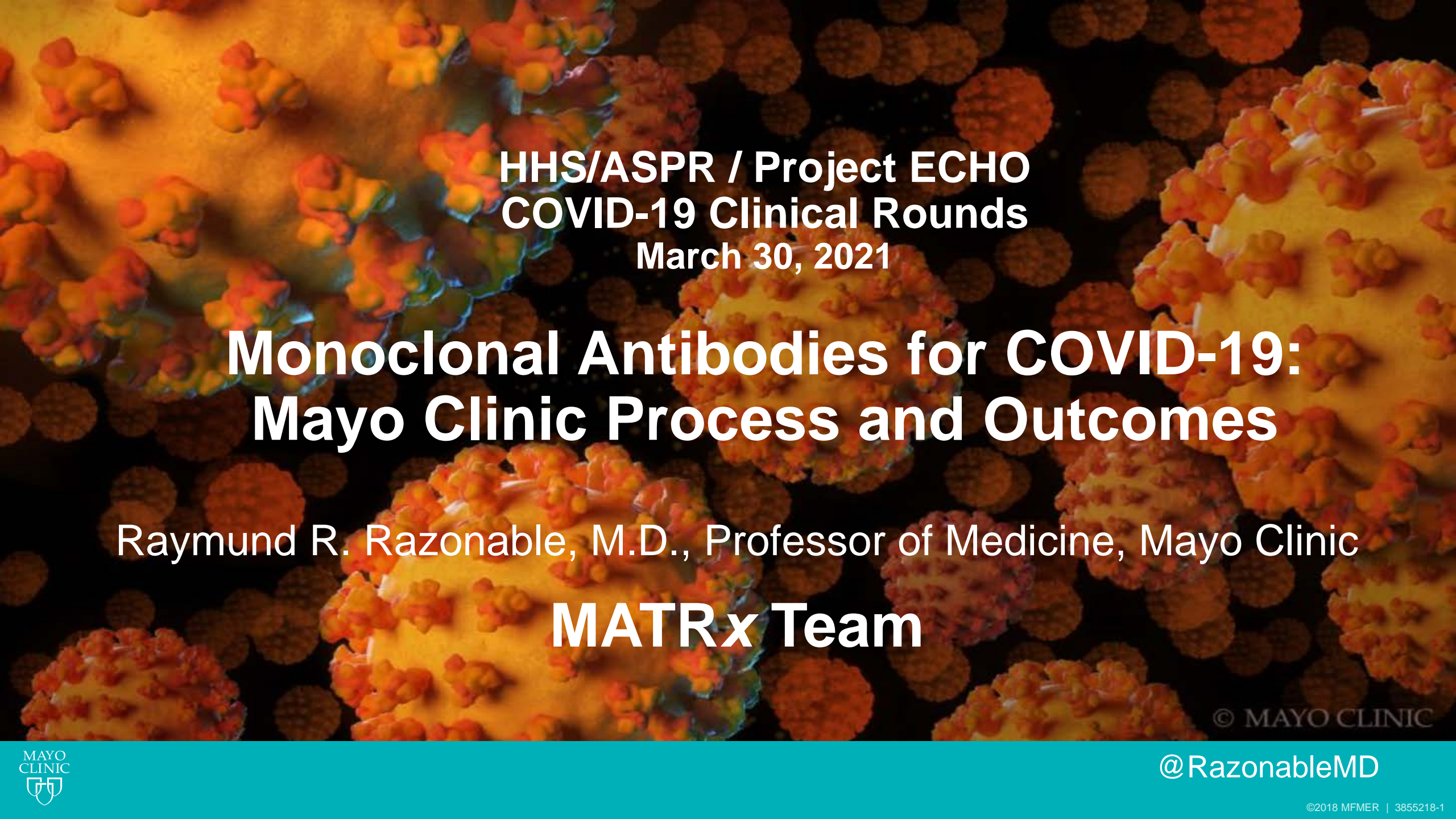
Early preliminary data: Mayo Clinic (unpublished)



Early preliminary data: Mayo Clinic (unpublished; not final data)

Conclusions: Mayo Monoclonal Antibody Program

- Effective and safe treatment option for high-risk patients with mild to moderate covid-19 in outpatient setting
- Program and process: multidisciplinary team, active > passive approach model, support of leadership, partnership with primary providers, physical and electronic infrastructure, flexibility and adaptability (mobile units, underserved persons)
- Real-time assessment of clinical outcomes to further guide our practice implementation

A microscopic view of several COVID-19 virus particles. The particles are spherical and covered in numerous small, orange, spike-like protrusions. They are set against a dark background with a bokeh effect of out-of-focus light spots in shades of orange and yellow.

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