Monoclonal Antibodies: Medical Uses for the Prevention and Treatment of Disease

Monoclonal antibodies are laboratory made proteins designed to act like human antibodies by binding to specific proteins in the body called antigens. These antigens may include proteins from cancers, bacteria, viruses, or inflammatory cells. Monoclonal antibodies can act to help our immune system recognize and destroy dangerous antigens such as viruses (Figure 1).

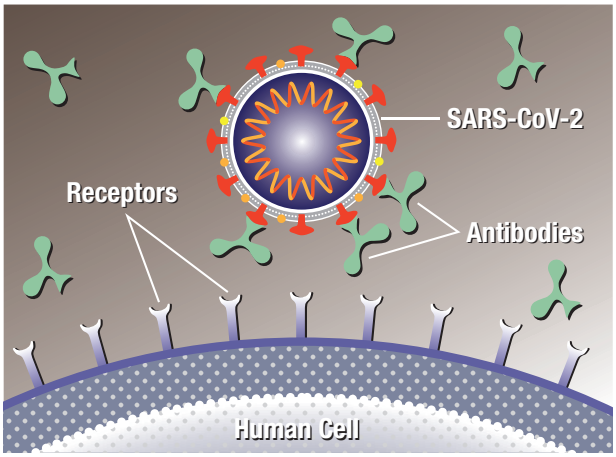

Figure 1: Image of an antibodies (green) binding to the surface of a SARS-CoV-2 virus and blocking entry of the virus into a human cell
Source: https://www.nih.gov/news-events/news-releases/clinical-trials-monoclonal-antibodies-prevent-covid-19-now-enrolling

The History of Monoclonal Antibodies

The idea of using a person's blood who has recovered from an illness to help another person recover from the same illness is not new. During the influenza virus pandemic of 1918, physicians would use blood serum from people who had recovered from influenza and administer it to those infected with influenza to prevent progression of disease.[1] This blood was believed to contain antibodies made by the immune system to detect and eliminate pathogens. Over the past century, numerous infectious diseases have been treated though this type of therapy including: Lassa fever, hemorrhagic fever, measles, and various respiratory viruses.

Through scientific advancement over the last 30 years, we are able to isolate and manufacture *specific* antibodies to fight a variety of diseases. These specific antibodies are called monoclonal antibodies. Currently there are over 30 monoclonal antibodies approved for use in medicine for various diseases. (Table 1)

Table 1. Monoclonal antibody uses in modern medicine.

Cancers	• leukemia • lymphoma • breast • lung • colon
Asthma	
Autoimmune Disorders	• Rheumatoid arthritis • Crohn's disease • Ulcerative colitis • Ankylosing spondylitis
Osteoporosis	
Kidney transplant rejection	
Infections	• Hepatitis C infection • Respiratory Syncytial Virus (children) • SARS-CoV-2 coronavirus

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Monoclonal Antibodies for SARS-CoV-2 (COVID-19 Infection)

On November 9, 2020, the FDA authorized the first monoclonal antibody against a spike protein on SARS-CoV-2 for treatment for mild-to-moderate COVID-19 in adult and pediatric patients in the outpatient setting.[2] The safety and effectiveness of this therapy is being further evaluated in clinical trials of patients with COVID-19.[3] All monoclonal antibodies that have been approved to date are for "emergency use." Emergency use authorization or "EUA" allows the FDA, during public health emergencies, to use an unapproved medical product based on the best available evidence, to treat or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, or available alternatives.[4]

Monoclonal antibodies were approved for emergency use in COVID-19 because there are clinical trial data showing reduction in harm from COVID-19. The approved monoclonal antibodies for emergency use in COVID patients are:

- casirivimab with imdevimab, and
- etesevimab with bamlanivimab.

These antibodies are often given in combination to improve effectiveness against resistant viral variants.[5] These are approved for people 12 years of age who weigh at least 40 kilograms (88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization. People considered at high risk include people who are 65 years of age or older, or people who have specified chronic medical conditions.

In addition to antibodies against the virus, there is also an monoclonal antibody being used in COVID-19 illness to target inflammation. With COVID-19 infection, there can be an intense reaction in the body including inflammatory proteins called cytokines. Targeting these cytokines with antibody treatment can reduce inflammation in the body. An example of this is tocilizumab which is used for patients with severe inflammation from COVID-19.

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Rx Action Steps

- ✔ Consider getting tested for COVID-19 if you develop symptoms during the pandemic (such as, cough, fever, shortness of breath, loss of smell)[6]
- ✔ Contact your doctor if you are tested positive for COVID-19 to see if you may qualify to get monoclonal antibodies to prevent severe illness.
- ✔ Talk with your healthcare provider about the risks and benefits of monoclonal antibody treatment if you have one of the diseases listed in Table 1.

Healthcare Provider's Contact Number:

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For More Information

American Thoracic Society

- www.thoracic.org/patients/

References

1. Garraud O. Use of convalescent plasma in Ebola virus infection. Transfus Apher Sci 2017;56:31-4.
2. FDA Monoclonal Antibody Approvals https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19
3. Chen P, Nirula A, Heller B, et al. SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19. N Engl J Med. Published online October 28, 2020.
4. Emergency Use Authorization https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained
5. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19-0
6. https://www.thoracic.org/patients/patient-resources/resources/covid-19-how-do-we-stay-safe.pdf