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COVID-19 Virtual Community Meeting: The Delta Variant and Staying Protected

September 24, 2021

9:00 AM PT, 10:00 AM MT,
11:00 AM CT, 12:00 PM ET

This program was made possible by grant support from

Speakers

Welcome: Patricia Koffman
Co-Founder and Communications Director
CLL Society

Moderator: Brian Koffman, MDCM (retired), MS Ed
Executive Vice President and Chief Medical Officer
CLL Society

Speaker: Robyn Brumble, MSN, RN
Director of Scientific Affairs
CLL Society

Speakers

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Daniel Engel, PhD
Professor of Microbiology,
Immunology and Cancer Biology
University of Virginia School of
Medicine

Nicole Lamanna, MD
Associate Professor of Clinical Medicine
Division of Hematology Oncology
Department of Medicine
Columbia University Medical College

Deborah Stephens, DO
Assistant Professor of Hematology
and Hematologic Malignancies
The University of Utah Health
The Huntsman Cancer Institute

Sanjeet Singh Dadwal, MD
Chief, Division of Infectious Diseases
City of Hope National Medical Center

Agenda

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12:00 PM ET Welcome, Overview, Panel Introductions, Audience Poll

12:05 PM CLL Society COVID-19 Plan

12:10 PM Panelist Comments

12:30 PM Audience Q&A with Panelists

1:25 PM Concluding Comments

CLL Society's COVID-19 Action Plan

Robyn Brumble, RN, MSN
Director of Scientific Affairs
CLL Society

Complete Prior to COVID-19 Exposure

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Directions for Completing the COVID-19 Planning Checklist

CLL Society highly encourages individuals living with CLL to prepare ahead of time and have a comprehensive COVID-19 Plan already in place just in case you have either a known exposure or receive a positive test result. The following are guidelines to assist you in completing your personalized COVID-19 Planning Checklist. Please keep all printed information in a designated COVID-19 Planning Folder that can be easily accessed if needed.

1) Obtain an oxygen (O2) pulse oximeter (O2 saturation monitoring device) and have it readily available in your home. Inexpensive O2 pulse oximeters can be purchased on Amazon or from your local drug store.
2) Have a reliable digital thermometer available. If you only have oral thermometers in your home, consider purchasing one for each member of the household to prevent spreading the virus to other family members.
3) Know ahead of time where you will go to get tested for COVID-19, and confirm they will perform the necessary testing:
   - The location you choose should be willing to offer you BOTH the rapid test and the PCR test at the same time. Remember, the Rapid test *can* indicate evidence of COVID-19 infection, but the PCR is typically more accurate. (Please also note, some rapid tests will not detect variants).
   - Always err on the side of caution and get tested right away should you experience *any respiratory symptoms*, or if you have known exposure to COVID-19. Do not dismiss allergy or cold symptoms!
   - The earlier you know, the earlier you can receive treatment, which is of utmost importance.
4) High titer convalescent plasma should be administered early after diagnosis and is authorized under the EUA (Emergency Use Authorization) for the treatment of **hospitalized** patients with COVID-19 and impaired immunity. That would include CLL patients. It is not used in severe COVID-19. Convalescent plasma may need to be administered more than once.
5) Monoclonal antibodies directed against the COVID-19 spike protein have proven to help high-risk patients and should be given **within 10 days** of diagnosis and can be given **outpatient**. The earlier the better! You *must* investigate ahead of time which hospitals in your area provide rapid access to this *critical* COVID-19 treatment! COVID-19 monoclonal antibody therapies are not available everywhere and are most likely *not* available at your local small community hospital. So please spend time finding out exactly where you can access them quickly should you need them. It is also important to understand the criteria that make you eligible for receiving this critical COVID-19 treatment should there be any pushback when you advocate for receiving it:
   - Search this map to find the hospitals in your area that have monoclonal antibody therapy available, and make it part of your plan to visit their emergency room if COVID-19 treatment becomes necessary.

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COVID-19 PLANNING CHECKLIST

Complete Prior To Exposure

Obtain Necessary Monitoring Supplies	☐ Oxygen Monitoring Device (Pulse Oximeter) ☐ Digital Thermometer for Each Individual in the Household
Know Where to Go for COVID-19 Testing	☐ Ensure Testing Facility Will Perform BOTH the Rapid Test & the PCR Test ☐ Name of Testing Location: _____
Determine Where Critical COVID-19 Treatments Are Available Nearby	☐ Convalescent Plasma: _____ ☐ Monoclonal Antibodies: _____
Healthcare Team Contact Information	☐ CLL Provider's Contact Info: _____ ☐ Create a List of All Healthcare Providers and Place in Planning Folder
Personal Paperwork to Place in COVID-19 Planning Folder	☐ List of All Medications, Vitamins/Supplements, & Vaccination Information ☐ Copy of Living Will, Power of Attorney, & Advance Directives ☐ Insurance Cards
CLL Society Documents to Place in COVID-19 Planning Folder	☐ CLL Society's Official Statement for Prioritizing CLL Patients Emergency Room Care related to COVID-19 ☐ Print CLL Society's Pre-COVID Exposure Planning Document
Quarantine Plan	☐ Complete Quarantine Plan Checklist and Place a Copy in Planning Folder ☐ Discuss Quarantine Plan with Others in the Household

Please Refer to the COVID-19 Planning Checklist Directions Sheet for Detailed Instructions

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Known Exposure, Positive Result, and How to Quarantine

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CHECKLIST FOR KNOWN EXPOSURE TO COVID-19 WITHOUT A POSITIVE TEST RESULT

READ THROUGH YOUR COVID-19 PLANNING FOLDER AND ACTIVATE YOUR HOUSEHOLD QUARANTINE PLAN

- ☐ Closely monitor for symptoms of COVID-19. Symptoms can appear anywhere from 2-14 days after exposure and may or may not include headache, fever or chills, cough, shortness of breath or difficulty breathing, increased fatigue, worsening muscle or body aches, headache, loss of taste or smell, sore throat, congestion, runny nose, nausea, vomiting, and diarrhea.
- ☐ Contact your healthcare provider(s) right away to arrange for possible urgent treatment with the anti-COVID-19 monoclonal antibodies, **regardless of whether or not you have had a positive test or symptoms.**
- ☐ Immediately schedule appointments for testing 3-5 days following the date of known exposure. Availability for testing can be limited during times of surging cases.

TESTING RECOMMENDATIONS FOR COVID-19

- ☐ The CDC recommends testing 3-5 days following the date of the known exposure, even without symptoms. But if you begin to have symptoms, arrange to get tested right away.
- ☐ If possible, have both the rapid and PCR tests performed. If both are not available, the PCR test is much preferred due to increased accuracy. Know that if you test negative, you were not infected *at the time* your sample was collected. The test result only means that you did not have COVID-19 *at the time of testing*. Continue to take steps to protect yourself and others by wearing a mask and distancing.
- ☐ If symptoms develop, but you had a negative test, you should immediately get retested. If you test positive, refer to the COVID-19 Action Plan for the next steps.

QUARANTINE RECOMMENDATIONS FOR CLL

- ☐ If you received a negative PCR test result AND if no symptoms have been detected during daily monitoring, quarantine can end after Day 10.
- ☐ For those that did not get tested and never experienced any symptoms of COVID-19, quarantine must last for the full 14 days following exposure.

Please visit cllsociety.org for more information.

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HOUSEHOLD QUARANTINE PLAN

Why Is It Important To Have a Quarantine Plan in Place Before You Become Infected with COVID-19?

Receiving a COVID-19 diagnosis can be stressful and confusing, especially if you are not prepared. Having a self-quarantine plan will help everyone in the household know exactly what to do should the virus infect someone within the home. In addition to this checklist, learn as much as you can *in advance* about standard infection control precautions that may help decrease the possibility of spread. Place this document within your COVID-19 planning folder to refer to if needed.

- ☐ **Have plenty of masks available.** Everyone in the household should plan on wearing a tightly-fitted mask (preferably an N-95) over their nose and mouth as much as possible, especially when in direct contact with anyone else in the home.
- ☐ **Keep your distance from others.** Stay in a designated room by yourself and use a bathroom separate from the one used by others in the household. Keep your bedroom and bathroom door closed when possible. Have someone else prepare meals and leave them outside your bedroom door.
- ☐ **Do not leave your home (unless necessary for medical care).** Identify family, friends, or community groups to help deliver groceries, medications, and other supplies to your front door. Have their contact information readily available as part of your quarantine plan.
- ☐ **If living with others, increase ventilation within your home.** Open windows and outside doors (when the weather permits), operate attic/window fans or run a window air conditioner with the vent control open to increase the indoor/outdoor airflow.
- ☐ **Have necessary supplies on hand.** Consider creating a kit that includes items such as thermometers for each person in the home, electrolytes, teas, over-the-counter medications, cleaning supplies, hand sanitizer, disposable gloves, Kleenex, etc. Speak with your healthcare provider about what vitamins or over-the-counter medications might be helpful to have readily available as well.
- ☐ **Wipe down high-touch areas every day with a disinfectant.** This includes doorknobs, light switches, phones, remote controls, appliances, sink, toilet, countertops, etc. Let someone else disinfect high-touch surfaces in the common areas of the home. But you should also clean and disinfect your designated sick room and bathroom if possible.
- ☐ **Do not share any items with others in your home.** This includes dishes, drinking glasses, eating utensils, towels, or bedding. It is important to wash all items used by the infected person thoroughly with soap and water after using them.

For more information, please visit cllsociety.org

What Do I Do If I Do Get COVID-19?

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COVID-19 ACTION PLAN

Do These Things After Testing Positive for COVID-19

ACTIVATE YOUR PLAN! ACT EARLY-EVEN IF YOU FEEL FINE. REMEMBER, TIME IS OF THE ESSENCE.

- ☐ Access your COVID-19 Planning Folder.
- ☐ Read through your COVID-19 Planning Checklist and Instructions again.
- ☐ Contact your healthcare provider(s) **immediately** to discuss arranging urgent treatment with the anti-COVID-19 monoclonal antibodies and any other possible early therapies **as soon as possible**.
- ☐ Activate your Household Quarantine Plan.

IMPORTANT PEOPLE TO CONTACT

- ☐ Contact anyone you have been around in the previous 48 hours and inform them of your positive test result. By notifying close contacts of possible exposure, you may be helping them prevent the spread of COVID-19 to their friends and family.
- ☐ Someone from the health department may call you. This is completely normal, and it is important to answer the call to assist with contact tracing, which may also help slow the spread.
- ☐ Call your healthcare provider(s) to notify them of your positive test result. Stay in touch with them periodically to ask questions and/or inform them of your status. And do not hesitate to call your healthcare provider(s) to report any symptoms that are severe or concerning to you.

SCHEDULED APPOINTMENTS

- ☐ If you have an in-person medical appointment that cannot be avoided, call the office ahead of time to remind them you have been diagnosed with COVID-19. This will help the office put measures in place to protect the staff and other patients when you arrive.

KEEP A LOG OF YOUR VITAL SIGNS AND SYMPTOMS

- ☐ Begin recording a list of all measured vital signs, especially oxygen saturation levels and temperatures
- ☐ Keep track of when you experience any new symptoms such as cough, chills, shortness of breath, fatigue, muscle/body aches, vomiting, diarrhea, or loss of taste/smell.
- ☐ Include the time and date when you are logging them.
- ☐ Call your healthcare provider(s) to inform them if your oxygen saturation is consistently reading below 95%, fever >100.4, or with worsening symptoms.

SEEKING EMERGENCY CARE

- ☐ Call 911 immediately if emergency warning signs for COVID-19 develop such as difficulty breathing, rapid breathing, oxygen saturation consistently reading <92%, persistent pain or pressure in the chest, difficulty staying awake, confusion, or discolored lips/nail beds.
- ☐ Should you need to seek emergency care via ambulance, you must request to be taken to the hospital that you have already determined ahead of time can provide you with rapid access to critical COVID-19 therapies. If they are not informed, they are required to transfer you to the nearest local hospital.
- ☐ Take your COVID-19 Planning Folder along with you to the hospital so you have quick access to the important documents (the "Official Statement for Prioritizing CLL Patient's Emergency Room Care").
- ☐ Most importantly, ADVOCATE for your best care! Remember, EARLY administration of critical COVID-19 therapies, such as convalescent plasma and SARS-CoV-2 monoclonal antibodies, is extremely important for those who are immunocompromised (as recommended by Emergency Use Authorization and other clinical guidelines). Data shows both reduced morbidity and mortality in CLL patients with both of these treatments.

AFTER YOUR DISEASE HAS RUN ITS COURSE

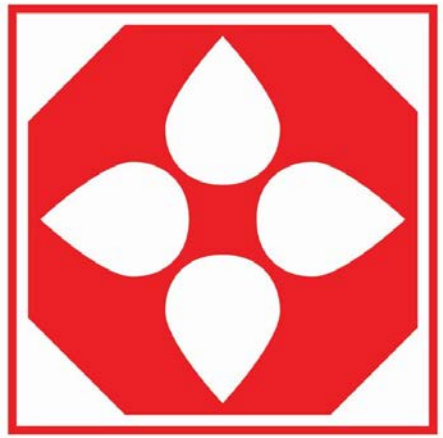
- ☐ Please consult with your healthcare provider(s) to find out when you can safely be around others. **If you have *any symptoms*, it is important to get tested again.** Routine testing after COVID-19 is not advised in the general population. However, your healthcare provider may recommend repeated testing, as some CLL patients have difficulty clearing the virus that causes COVID-19 and *may remain contagious* after symptoms resolve.

Please visit cllsociety.org for more information.

Where to Find the COVID-19 Action Plan On CLL Society's Website

Important Takeaways

- Complete the checklists ahead of time-BE PREPARED!
- Keep them in an easily accessible place, such as a folder
- Discuss your plan with others within the household
- If you have known exposure, symptoms, or a positive test result-pull out the plan and act fast! Time is of the essence.



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What to Know About SARS-CoV-2 Variants

Dan Engel, PhD
University of Virginia

Topic: Variants of SARS-CoV-2

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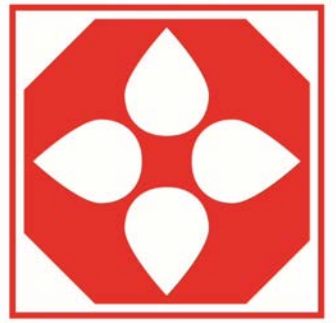
- A few words about how variants arise
- Will there be new variants?
- Is there anything we should do to stay protected against new variants?
- Variants and vaccination
- Variants and monoclonal antibody therapy
- Mask, mask, mask

American Society for Virology

COVID-19 Vaccine Education

VIRTUAL TOWN HALL



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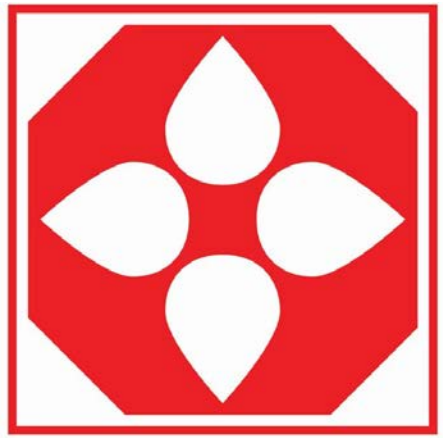
Please visit asv.org/education for more information, and to register



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COVID-19 Vaccine Response in CLL

Deborah Stephens, DO
The University of Utah Health
The Huntsman Cancer Institute

Response to COVID-19 Vaccine

- Responses to Pfizer Vaccine
  - Overall response (detected by antibody) was 40% in CLL Patients
    - Patients in Remission: 79%
    - Patients on “watch and wait”: 55%
    - Patients on any kind of treatment: 16%

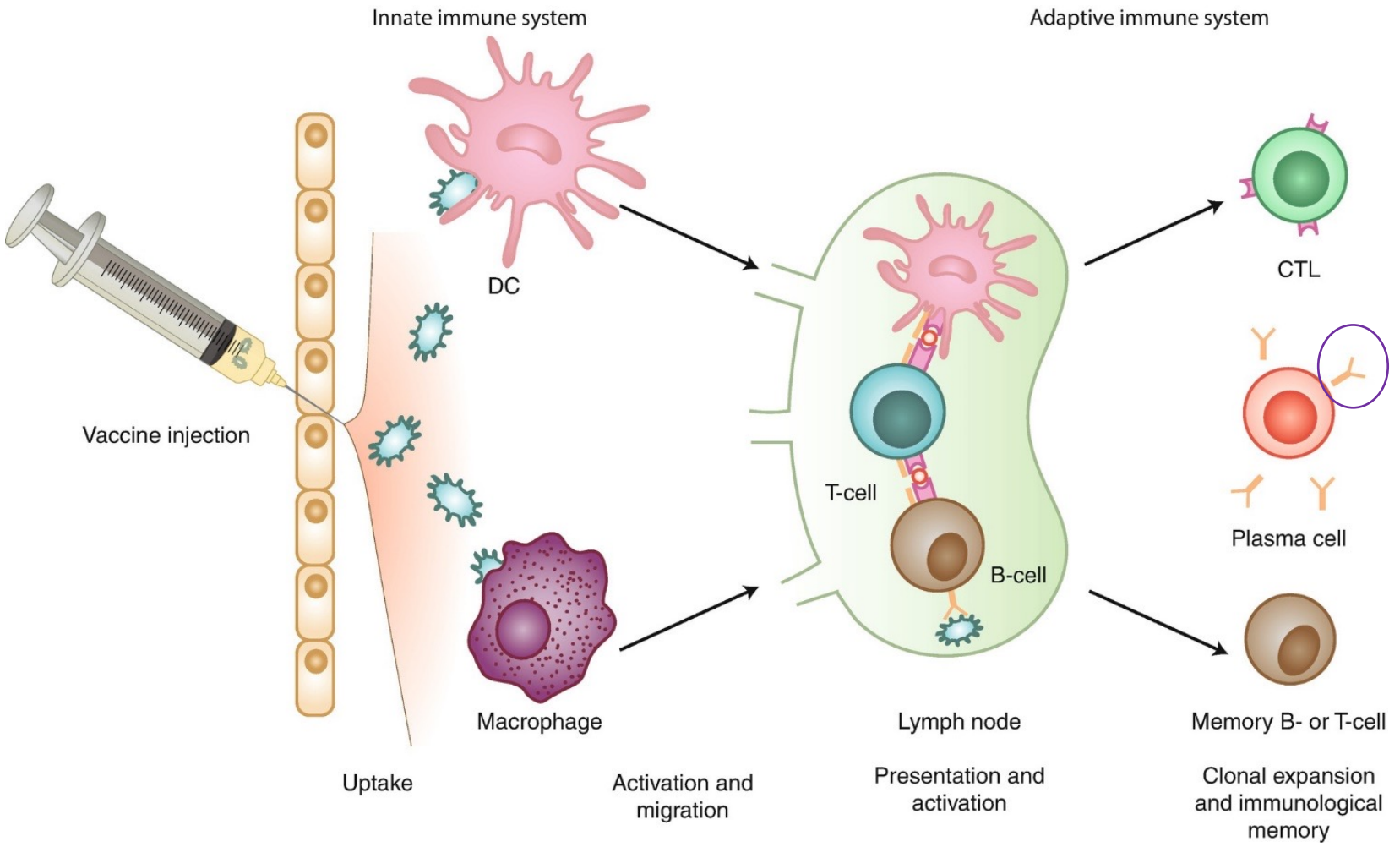
Herishanu, Blood 2021

Response to COVID-19 Vaccine

- Responses to Pfizer or Moderna Vaccine
  - Antibodies Detected: 52% in CLL Patients
    - Patients Never Treated: 94%
    - Patients with Prior Treatment: 23%
      - Ibrutinib/acalabrutinib Treatment: 21%
      - Rituximab/obinutuzumab within 12 months: 14%
      - Rituximab/obinutuzumab + venetoclax within 12 months: 0%
  - Younger (<70) or no prior treatment: more likely to develop antibodies

Roeker, Leukemia 2021

Different Parts of Immune System Needed for Vaccine Response



Antibodies are easiest to measure

Jiskoot, Pharmaceutical Biotechnology 2019

Recommendation

- Likely responses outside of antibodies that are not easily measurable
- Risks of severe complications of COVID-19 outweigh any risks of vaccination
- **Recommend all CLL patients receive a COVID-19 vaccine**
  - If initially received Pfizer/Moderna: Recommend a booster shot of same vaccine (Pfizer/Moderna)
- **Must continue to be vigilant with masking, washing hands, social distancing (without social isolation)**

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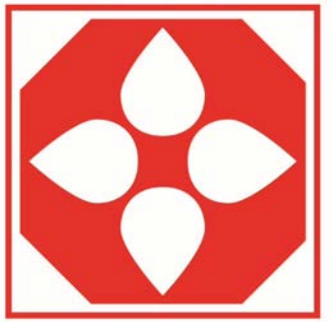
What If I Am Infected with COVID-19?

Nicole Lamanna, MD
Columbia University Medical College

If a CLL Patient Becomes Infected with COVID-19, What Are the Immediate Next Steps? What Treatments Should They Be Asking For?



- STAY CALM!
- Refer to your COVID plan (https://cllsociety.org/2021/07/covid-19-plan-checklists-for-chronic-lymphocytic-leukemia-cll-preparing-for-pre-and-post-covid-19-exposure/)
- Contact your treating physician (CLL doctor, or other)
- Make arrangements to receive monoclonal antibody therapy!
  - Antibodies approved through EUA include: Regeneron, Eli-Lilly, GSK (availability may differ depending upon location)
  - Need to receive in a timely fashion after positive test results OR recent post-exposure prophylaxis (ideally within 24-72 hours)
- Self-quarantine *except* to get tested/receive antibody therapy (if you are living with other individuals, they should be tested and self-quarantine as well)

How Do Monoclonal Antibody Therapies Work Against COVID-19?

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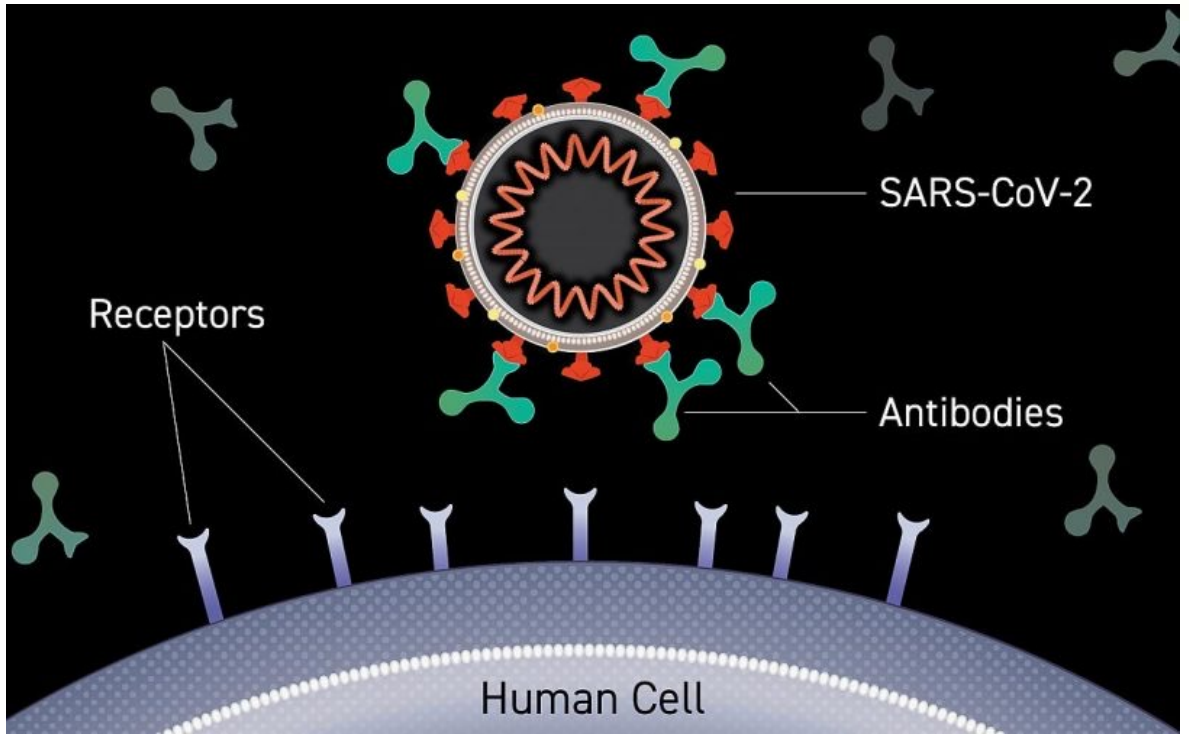
- Monoclonal antibodies against COVID-19 attach to the virus to block it from entering human cells
- The monoclonal antibody protein also “marks” the virus to be broken down by the immune system and cleared from the body.



Monoclonal Antibody Therapies for COVID-19

(Regeneron, Eli Lilly, GSK)

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FDA emergency use authorization (EUA) of this treatment for:

1. Mild-moderate COVID-19 in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with ***positive results of direct SARS-CoV-2 viral testing.***
2. Adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for **post-exposure prophylaxis** with Regeneron or Eli Lilly monoclonal *a*ntibodies of COVID-19 in individuals who are:
   - Not fully vaccinated **OR** who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) **AND**
   - Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC) **OR**
   - Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons)

Monoclonal Antibody Therapies for COVID-19

(Regeneron, Eli Lilly, GSK)

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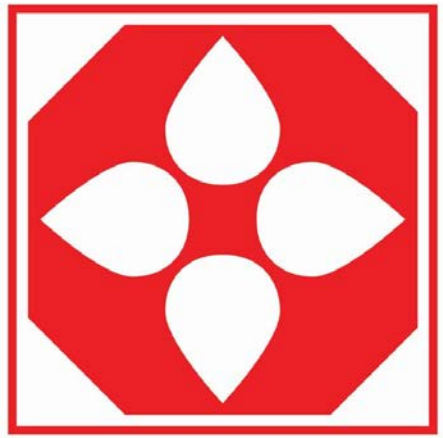
- Typically given as IV infusion (approximately one hour for infusion, but whole process 2-3 hours for monitoring etc.); some can be given subcutaneously (SQ)
- These infusions are generally well-tolerated!
- An infusion-related reaction could occur and symptoms may include:
  - Fever; chills; nausea; headache; shortness of breath; low blood pressure; wheezing; swelling of your lips, face, or throat; rash, including hives; itching; muscle aches; and/or dizziness



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Management of COVID-19 in Hospitalized CLL Patients: What to Expect

Sanjeet, Dadwal, MD, FACP
City of Hope National Medical Center

Treatment Recommendations from Infectious Diseases Society of America (IDSA)

- Treatment guidance is for general public – lack of data/ recommendations in immunocompromised patients

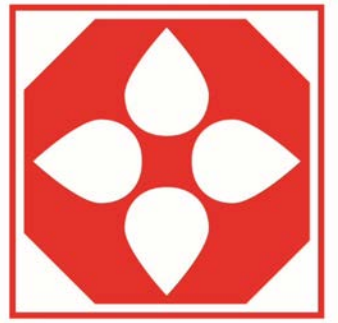
- Treatment guidance is lacking for immunocompromised patients due to lack of clinical trial data

- Treatment based on disease severity:
  - Mild to moderate
  - Moderate to severe
  - Critically ill
  - Severe illness (defined as oxygen saturation less than 94%)

Treatment Options

- Anti-viral drugs:
  - Remdesivir is the only FDA approved anti-viral drug
  - Ongoing studies:
  - Molnupiravir – in phase 3 trial treating non-hospitalized patients with intent to prevent progression to severe disease and hospitalization. This may become available under EUA by end of this year
- Anti-inflammatory approach:
  - Reserved for severe and critically ill (requiring supplemental oxygen)
    - Decadron
    - IL-6 inhibitors: Tocilizumab or Sarilumab or Baracitinib or Tofacitinib

Monoclonal Antibodies/ High Titer COVID-19 Convalescent Plasma (CCP)



- Monoclonal antibodies (3 are EUA approved):
  - EUA for use in post-exposure prophylaxis (only Casirivimab/ Imdevimab)
  - EUA for treatment of mild to moderate non-hospitalized patients or if hospitalized for reasons other than COVID-19
  - Not recommended for patients hospitalized for COVID-19, especially severe illness. Discussion can be done with FDA and the sponsor for emergency IND to treat in special situations
- CCP, COVID-19 Convalescent Plasma:
  - Not recommended for severe disease in general population
  - Small studies suggest benefit in immunocompromised patients, especially those receiving anti-B cell therapies (e.g., CLL, lymphoma patients)

Ask for Clinical Trials if Available

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Ask your treating MD

www.clinicaltrials.gov

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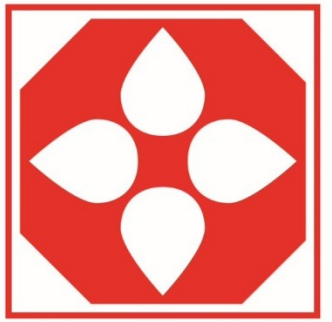
Audience Questions & Answers

This program was made possible by grant support from

Thank You for Attending!



Please take a moment to complete our **post-event survey**, your feedback is important to us

Join us on October 15th for the
CLL Society Ed Forum: The Right Tests at the Right Time

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