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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2020 #36 **October 16, 2020**

INSIDE:

NIH-sponsored Hyperimmune Intravenous Immunoglobulin Trial to Treat COVID-19 Begins

The National Institutes of Health (NIH) announced last week that the clinical trial to determine the "safety, tolerability, and efficacy of a combination treatment regimen" of an hyperimmune intravenous immunoglobulin (hIVIG) and the antiviral drug remdesivir to treat COVID-19 has begun. "Finding safe and effective treatments for COVID-19 is absolutely critical," said NIH National Institute of Allergy and Infectious Diseases (NIAID) Director Anthony S. Fauci, MD in an agency news release. "The [Inpatient Treatment with Anti-Coronavirus Immunoglobulin] ITAC trial will examine whether adding anti-coronavirus hIVIG to a remdesivir regimen can give the immune system a needed boost to suppress SARS-CoV-2 early in the course of illness, nipping the infection in the bud." Members of the CoVIg-19 Plasma Alliance collaborating with NIH for the trial include:

- Emergent BioSolutions;
- Grifols S.A.;
- CSL Behring; and
- Takeda Pharmaceuticals.

"The rapid progress we've made since we initiated this program just a few months ago to reach this key milestone of enrolling patients in the trial is a powerful testament to the collaboration, determination and innovation taking place across the biomedical community as we work to fight the COVID-19 pandemic," said Julie Kim, President of Plasma-Derived Therapies Business Unit, Takeda and co-leader of the CoVIg-19 Alliance in an alliance news release. "This study will help us understand how CoVIg-19 could potentially become an important therapeutic option. To support our efforts, we encourage all those people who have recovered from COVID-19 to donate their plasma, which contains vital antibodies that have fought off the disease and could help others do the same."

The trial will be randomized, a global multi-center, double-blind, and placebo controlled. It will include 500 adult patients "who have been hospitalized for COVID-19 and have had symptoms for 12 days or fewer without life-threatening organ dysfunction or end-organ failure. Patients will receive remdesivir as standard of care, allowing the safety and efficacy of [hIVIG] to be evaluated when given along with remdesivir treatment." Bill Mezzanotte, MD, MPH, executive vice president, head of Research and Development and chief medical officer for CSL Behring, co-leader of the CoVIg-19 Alliance, added. "When we created the CoVIg-19 Plasma Alliance in April, the goal was to partner to accelerate our timelines so that we could develop

(continued on page 2)

hIVIG NIH-sponsored COVID-19 Trial Begins (continued from page 1)

and deliver a reliable and sustainable treatment option for people suffering the impact of COVID-19 and to support countries around the world in their efforts to fight the current pandemic. Thanks to the unprecedented collaboration from the CoVIg-19 Plasma Alliance members, commitment from those who have recovered from the virus and generously chosen to donate their plasma, as well as the strong support from the NIH, we are hopeful that data from the clinical trial will be available before the end of the year. If the trial proves successful, this therapy could bring new hope to those suffering serious health consequences from COVID-19."

The COVIg-19 Plasma Alliance is also members of the coalition for "The Fight Is In Us" campaign, which calls attention to the need for individuals who have recovered from COVID-19 to donate convalescent plasma. America's Blood Centers is part of the campaign coalition of medical and research institutions, blood centers, life science companies, technology companies, philanthropic organizations, and COVID-19 survivor groups that have collaborated on the campaign to support the rapid development of potential new therapies for patients with COVID-19. The organizations hope to mobilize tens of thousands of people in the U.S. who have recovered from COVID-19 to donate convalescent plasma. The coalition offers more than 1,500 locations at which COVID-19 survivors can choose to donate. Donations can be made at both blood and plasma donor centers.

(Source: NIH News Release, 10/8/20; COVIg-19 Plasma Alliance News Release, 10/8/20)

Upcoming ABC Webinars – Don't Miss Out!

- **ABC QA Education Webinar: ABC Platelet Bacterial Detection Plans Survey Results & Way Forward** – October 20th from 3 – 4:30 p.m. (EDT). Contact ABC for additional details or see MCN 20-091.
- **ADRP Webinar: How to Get The Most out of Donor Promotions and Incentives** – October 28th from 1 – 2 p.m. (EDT). Register here.
- **ABC SMT Journal Club Webinar** – December 3rd from 12 – 1 p.m. (ET). Additional details coming soon.

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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BRIEFLY NOTED

U.S. Department of Health and Human Services (HHS) Secretary Alex Azar announced that the public health emergency for COVID-19 has been extended for another 90 days. He stated in an Oct. 2nd tweet, "[I just renewed the COVID-19 national public health emergency declaration, effective October 23, 2020. We will continue our whole-of-America response to the virus and continue our work to ensure Americans have access to the care they need." The declaration was scheduled to expire later this month and this extension will continue the public health emergency into January 2021. The declaration allows the Administration to provide response aid to local state health departments in addition to flexibility for government-run health insurance programs and emergency approvals of new drugs and tests.

(Source: HHS Announcement, 10/2/20)

Commonwealth Transfusion Foundation (CTF) recently awarded grants in transfusion medicine to Blood Centers of America, Inc. (BCA) ($200,000) and to clinical laboratory science programs at Augusta Health ($55,748), Old Dominion University ($141,625), and Virginia Commonwealth University (11,500). The grant to BCA will support the Geodatabase Optimization for the Location of Donors (GOLD) suite of analytic tools that provides actionable data to help identify new blood center locations, enhance operational efficiency, and optimize marketing strategies for blood donations. CTF states that the grant award "reflects [its] commitment to research on novel approaches to donor recruitment to ensure an adequate, post pandemic blood supply in the U.S. The clinical laboratory science program grants will help the recipient organizations update and improve their immunohematology student laboratories as the U.S. Bureau of Labor Standards expects the need for clinical technologists and technicians is expected to grow 11 percent by 2028. CTF hopes this grant "will help ensure students enrolled in these programs are trained on current blood banking technology so that they are better prepared to enter the workforce."

(CTF Announcement, 10/13/20)

The National Academies of Sciences, Engineering, and Medicine (NASEM) is holding a webinar on October 21st to discuss stakeholder feedback on the report titled "Addressing Sickle Cell Disease [SCD]: A Strategic Plan and Blueprint for Action" that was published last month. The report "recommends medical and social support to ensure a safe transition from pediatric to adult SCD care; metrics to assess the quality of SCD care; and new payment models for currently available and pipeline treatments." Highlights of the report are available here. The report outlines eight strategies as part of a strategic plan for addressing SCD moving forward:

- establish a national system to collect and link data to characterize the burden of disease, outcomes, and the needs of those with SCD across the life span;
- establish organized systems of care that ensure both clinical and nonclinical supportive services to all persons living with SCD;
- strengthen the evidence base for interventions and disease management and implement widespread efforts to monitor the quality of SCD care;
- increase the number of qualified health professionals providing SCD care;
- improve SCD awareness and strengthen advocacy efforts through targeted education and strategic partnerships among the U.S. Department of Health and Human Services; health care providers, advocacy groups, community-based organizations, professional associations, and other key stakeholders (e.g., media and state health departments);
- address barriers to accessing current and pipeline therapies for SCD;
- implement efforts to advance understanding of the full impact of sickle cell trait on individuals and society; and
- establish and fund a research agenda to inform effective programs and policies across the life span.

(Source: NASEM Webinar Announcement, 10/14/20; Report Announcement, 9/10/20) ♦

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) recently published new Biological Product Deviation Reporting (BPDR) and HCT/P Reporting Codes which can be accessed on the FDA website. Changes made on Oct. 1 are marked with a dagger (†). These codes are used to report errors and accidents in the manufacturing of biological products and the new BPDR codes should be reviewed for relevant changes as these may alter their reporting requirements.

(Source: FDA Announcement, 10/2/20) ♦

RESEARCH IN BRIEF

Trends in Diagnosis of HIV Infection, Linkage to Medical Care and Viral Suppression Among Men Who Have Sex With Men (MSM). The U.S. Centers for Disease Control and Prevention's (CDC) *Morbidity and Mortality Weekly Report* recently published the results of a study that examines trends in HIV infection in MSM. During 2018, MSM accounted for "69.4 percent of all diagnoses of human immunodeficiency virus (HIV) infection in the United States stated a study in…[P]ercentages of MSM linked to care within one month [of diagnosis] (80.8 percent) and virally suppressed (viral load <200 copies of HIV RNA/mL) within six months (68.3 percent) of diagnosis were below target during 2018." The researchers found that, "African American/Black (Black), Hispanic/Latino (Hispanic), and younger MSM disproportionately experience HIV diagnosis, not being linked to care, and not being virally suppressed…[T]he CDC analyzed National HIV Surveillance System data from 2014 to 2018." The authors state that, "[t]he diagnoses of HIV infection among all MSM decreased 2.3 percent per year…[D]iagnoses did not significantly change among either Hispanic MSM or any MSM aged 13–19 years[but did increase] 2.2 percent and 2.0 percent per year among Black and Hispanic MSM aged 25–34 years, respectively; and were highest in absolute count among Black MSM." The researchers also wrote that the "[a]nnual percentages of linkage to care within one month and viral suppression within six months of diagnosis among all MSM increased (2.9 percent and 6.8 percent per year, respectively)." They noted that "[i]ncreased linkage to care promotes viral suppression, which effectively prevents HIV transmission…[A]mong all MSM, only 67.2 percent achieved viral suppression within six months of diagnosis…Moreover, proportionally fewer Black MSM were linked to care and achieved viral suppression than did other racial/ethnic MSM groups." The authors acknowledge "limitations" such as "only 33 of the 51 U.S. jurisdictions had complete laboratory reporting of CD4 and viral load results [and] data do not represent all diagnoses of HIV infection…[D]uring 2017, Black and Hispanic MSM who had discussed preexposure prophylaxis with a medical provider were less likely than were White MSM to receive prescriptions for preexposure prophylaxis." The researchers state that "[p]roviders' implicit racial biases toward Blacks and Hispanics often promote treatment nonadherence, which inhibits viral suppression." They suggest "[i]nterventions might need to address systemic racism and concomitant racial biases within health care systems…Such interventions might help prevent HIV infection and eliminate racial/ethnic disparities in HIV infection among MSM."

Citation: Jeffries, W.L., Dailey, A.F., Jin, C., *et al*. Trends in Diagnosis of HIV Infection, Linkage to Medical Care, and Viral Suppression Among Men Who Have Sex with Men, by Race/Ethnicity and Age — 33 Jurisdictions, United States, 2014–2018. *MMWR*. 2020. 69 (38): 1337-1342.

Contributed by Richard Gammon, MD, Medical Director at OneBlood ♦

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The calendar of events includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

America's Blood Centers®
It's About *Life.*

INSIDE ABC

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.

2020 Financial Ratio Survey Deadline Extended

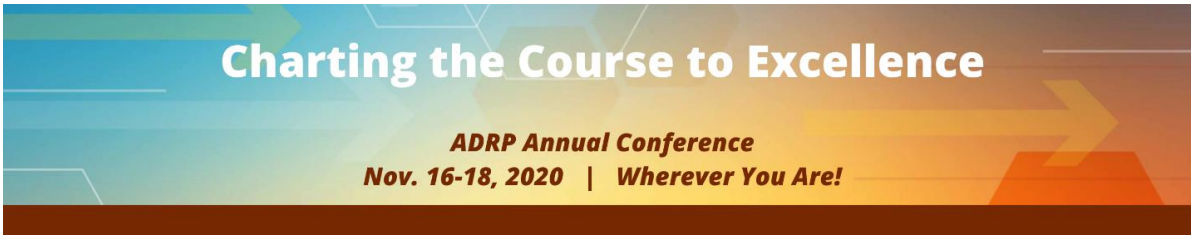
The deadline to participate in the 2020 ABC Financial Ratio Survey has been extended to October 23rd. ABC members are encouraged to take part as the results provide members with a powerful tool for managing blood programs, benchmarking valuable operational data, and identifying best practices. The survey is now conducted as part of a newly developed schedule to ensure that benchmarking surveys are spread throughout the year and can be planned accordingly. Most of the financial information requested is public information that blood centers already report on IRS Form 990 or is included in annual audited financials. Only participating blood centers receive the final report. Please contact Jill Evans with any questions or comments or for more details and MCN 20-088.

Webinar: ABC Platelet Bacterial Detection Plans Survey Results & Way Forward

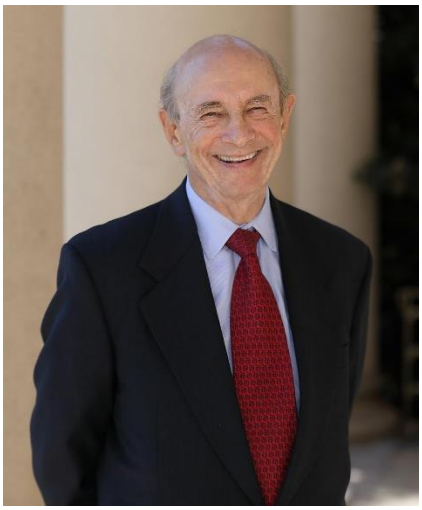
The next ABC QA Education Webinar titled "ABC Platelet Bacterial Detection Plans Survey Results & Way Forward" will take place on Tuesday, October 20th from 3 p.m. EDT to 4:30 p.m. During this event, ABC will review the survey results and discuss advocacy recommendations to support ABC member blood center implementation. Please contact Toni Mattoch for additional details on MCN 20-091 including a link to the webinar.

ADRP Annual Conference Goes Virtual

Register today for the ADRP Annual Conference, now a virtual event. The dates may have changed, but the content has not! Please plan to join us November 16th-18th. Over the course of three days, individuals will have access to abstract presentations, roundtables, and an interactive virtual exhibit hall. As an attendee, you will be able to use the virtual conference platform for one year and have the opportunity to experience all of the sessions that you may not have been able to participate in at an in-person conference, an increase of more than 10 education hours! This event will benefit blood center staff in multiple disciplines including donor recruitment, collections, marketing, and communications. We encourage staff from all levels to attend, to enhance the collaboration within their individual donor center. Group discount rates are available for ADRP subscribers. More information is available here. The full conference program can be viewed here.



PEOPLE



National Institutes of Health's (NIH) researcher **Harvey J. Alter, MD** has been awarded a 2020 Nobel Prize in Physiology or Medicine for his contributions to the discovery of the hepatitis C virus. "I am overwhelmed at the moment, but so pleased that this originally obscure virus has proven to have such a large global impact," said Dr. Alter in a news release. "There are so many persons at NIH who advanced my research, but for now I can only thank NIH, itself, for creating the permissive and collaborative environment that supported these studies over the course of decades. I don't believe my contributions could have occurred anywhere else." NIH Director Francis S. Collins, MD, PhD added, Harvey Alter is a scientist's scientist — smart, creative, dedicated, persistent, self-effacing, intensely dedicated to saving lives. His work to identify the nature of the hepatitis C virus has led to dramatic advances in protecting the blood supply from this very serious illness, and ultimately to the development of highly successful therapy." Dr. Alter's more than 50-year distinguished career at NIH began in 1961 followed by a stint at Georgetown University before returning to NIH in 1969. He has also been recognized during his career with the Albert Lasker Clinical Medical Research Award in 2002, the appointment as an NIH Distinguished Investigator (one of only 23 scientists to receive the designation), and the Canada Gairdner International Award. Dr. Altar holds a medical degree from the University of Rochester Medical School and was trained in internal medicine at Strong Memorial Hospital and the University Hospitals of Seattle. He is currently a Senior Scholar at the NIH Clinical Center's Department of Transfusion Medicine.

(Source: NIH Announcement, 10/5/20)

David Green, MSA, president and chief executive officer of Vitalant recently began his term as President of AABB. "I have been a member of AABB for almost 30 years," said Mr. Green in an AABB news release. "It is truly an honor to continue to serve the transfusion medicine and biotherapies community now as President of this Association. I am particularly impressed at how quickly our community has been able to adapt and overcome so many of the challenges posed by the ongoing COVID-19 pandemic, and look forward to working with AABB members as we continue to ensure the safety of donors and patients worldwide during these demanding times." He succeeds Beth Shaz, MD whose term concluded during the 2020 AABB Virtual Annual Meeting.

(Source: AABB News Release, 10/5/20) ♦

MEMBER NEWS

New York Blood Center (NYBC) is partnering with GoodCell to examine the role of "specific acquired and inherited genetic variations in blood" impacting COVID-19 severity and recovery. "Our blood and cells contain a vast network of information essential to defeating this virus," said Trevor Perry, Co-Founder and Chief Executive Officer, GoodCell in joint news release. "As hubs for these materials, blood centers play an invaluable role in the fight. We continue to be inspired by New York Blood Center's efforts to accelerate COVID-19 exploration on several fronts, from research to community recruitment of blood and convalescent plasma donors. Its partnership is a true testament to the potential of our susceptibility test, and we look forward to embarking on this journey with a collaborator that shares our mission to harness the power of

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MEMBER NEWS (continued from page 6)

blood to improve quality of life for all." The researchers will explore COVID-19 risk and susceptibility factors that could potentially aid in the development of a "susceptibility test" states the news release. "We are very excited to be working with GoodCell to understand a condition for which researchers have barely scratched the surface, especially as it relates to COVID-19," said Larry Luchsinger, PhD, head of the Laboratory of Stem Cell Regenerative Research, director of the NYBC iPSC Program, and Principal Investigator, Assistant Member at the Lindsley F. Kimball Research Institute in the news release. "Although CH is highly prevalent in adults, its causes and effects are still largely unknown. Establishing an association with COVID-19 will prompt a closer look at the condition as a means to prevent mortality and to better personalize treatment approaches. GoodCell's unique technology platform to study genetic variation in blood over time, paired with our access to donor samples, has the potential to be a powerful combination to evaluate this condition within the context of COVID-19 and further tip the scales against this virus." GoodCell Chief Medical Officer Salvatore Viscomi added, "[u]nderstanding the role of accumulated genetic variation in addition to inherited genetic variants will be critical in identifying individuals predisposed to severe COVID-19 complications. Validating the genetic variations associated with CH could be utilized as a disease modifier that could answer so many questions that still remain about COVID-19, such as why some patients are more responsive or refractory to treatments and why some patients undergo more rapid disease progression. We believe our work with NYBC is foundational to accelerating this research and will advance collective efforts to create a commercial COVID-19 susceptibility test."

(Source: New York Blood Center and GoodCell News Release, 10/5/20)

Héma-Québec researchers recently had findings from a small study examining the presence of antibodies in recovered COVID-19 patients donating convalescent plasma published in *Blood* as a research letter. "While many clinical trials are underway to better understand whether convalescent plasma is clinically beneficial for treating COVID-19, a key question is at what time point is it most effective to collect donor plasma based on the presence of antibodies that help fight the virus," said Renée Bazin, PhD, author of the study, in an American Society of Hematology (ASH) news release. "Based on our findings, antibodies against the new coronavirus are not eternal…The antibodies disappear rapidly, so people recovering from COVID-19 who want to donate blood plasma should not wait too long once they become eligible to donate." Study participants consisted of 11 males and four females who donated convalescent plasma between four and nine times between 33- and 77- days after their COVID-19 symptoms began with their final donation occurring between 66- and 114-days following symptom onset. The news release notes that, "the decline in antibodies over time appears unrelated to the number of times someone donated blood plasma and is, instead, due to the elapsed time since the infection and a natural waning of the immune response. All 15 donors showed decreases in antibodies at the same time, around 88 days, and half of the detectable antibodies decreased within 21 days afterward."

(Source: ASH News Release, 10/1/20) ♦

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste and published after editorial review. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

INFECTIOUS DISEASES UPDATES

EBOLA

The U.S. Food and Drug Administration (FDA) announced that it has approved its first treatment for Ebola. The Regeneron monoclonal antibody treatment (Inmazeb) has received agency approval for use in adult and pediatric patients. "Today's action demonstrates the FDA's ongoing commitment to responding to public health threats — both domestically and abroad—on the basis of science and data," said FDA Commissioner Stephen M. Hahn, MD in an agency news release. "This approval was made possible because of our steadfast dedication to facilitate the development of safe and effective treatments for infectious diseases as part of our vital public health mission." John Farley, MD, MPH, director of the Office of Infectious Diseases in the FDA's Center for Drug Evaluation and Research added, "[t]oday's approval highlights the importance of international collaboration in the fight against Ebola virus. The urgent need for advanced therapies to combat this infectious disease is clear, and today's action is a significant step forward in that effort. The World Health Organization (WHO) warned last month of a new outbreak (the 11th) of Ebola in the Democratic Republic of the Congo (DRC) that was spreading to other provinces and could soon reach neighboring countries. Earlier this summer, the WHO announced the 10th outbreak in the DRC was officially over. It resulted in 3,470 confirmed cases and 2,287 confirmed deaths. "Since 2015, BARDA has partnered with Regeneron to develop a life-saving treatment for Ebola Zaire", said Gary Disbrow, the acting Director of BARDA in a Regeneron news release. "The [FDA's] approval of Inmazeb shows the power of public private partnerships to bring forward these critical treatments and improve global public health. BARDA is continuing our collaboration with Regeneron on other life-threatening diseases such as MERS and COVID-19, and we look forward to continued success."

(Source: FDA News Release, 10/14/20; Regeneron Pharmaceuticals, News Release, 10/14/20; *UN News*, WHO warns against potential Ebola spread in DR Congo and beyond, 9/11/20) ♦

COMPANY NEWS

Cerus Corp. has been awarded a five-year contract valued at $11.1 million by the U.S. Food and Drug Administration (FDA) "for the development of next-generation compounds to optimize pathogen reduction (PR) treatment of whole blood to reduce the risk of transfusion-transmitted infections." In a Cerus news release, Nina Mufti, PhD, lead for the company's whole blood and red blood programs, said, "[w]e appreciate the FDA's support of Cerus' research program for whole blood PR technology. A whole blood PR solution would complement Cerus' portfolio of marketed pathogen reduction products for platelets and plasma, as well as its INTERCEPT Red Blood Cell (RBC) program that is in late-stage clinical development in the U.S." Anil Bagri, MD, PhD, vice president or Research and Pre-clinical Development at Cerus added, "This whole blood research effort could enable Cerus potentially to discover and develop the next generation of pathogen reduction technology to provide comprehensive safety solutions for transfusable blood components. We welcome FDA's support in enabling Cerus to bring this vision to reality."

(Source: Cerus Corp. News Release, 10/13/20)

QualTex Laboratories, a subsidiary of BioBridge Global, announced a recent expansion of services to include cellular therapy testing "in support of advanced therapeutics clinical developers." According to a company news release, the new offerings from QualTex will include:

- "analytical assay development;
- cell line characterization;
- expandability and potency testing;
- lot and final release assays; and
- stability testing."

BioBridge Global Chief Executive Officer Martin Landon stated in the news release, "[t]he launch of our cellular testing services provides another expansion to our end-to-end capabilities supporting regenerative and personalized medicine here in San Antonio, [Texas] and across the globe." QualTex Chief Operating Officer Ward Carter added, "[w]e have quality processes in place allowing us to provide phase-appropriate and risk-based testing solutions assuring the safety, purity, and potency of cell-based products."

(Source: QualTex Laboratories News Release, 10/13/20)

The National Institutes of Health-sponsored ACTIV-3 clinical trial for **Eli Lilly and Company's** LY-CoV555 neutralizing antibody therapy to treat COVID-19 in hospitalized patients has been paused following a recommendation from the independent data safety monitoring board of the clinical trial. A report in the *New York Times* indicated that a "potential safety concern" was the reason for the pause. Earlier this month, Eli Lilly and Company announced interim data from a combination therapy clinical trial for its two SARS-CoV-2 neutralizing antibody therapies (LY-CoV555 and LY-CoV016) and that it had requested emergency use authorization (EUA) from FDA for treating higher risk COVID-19 patients with LY-CoV555 monotherapy based on the findings from the combination therapy trial and "previously disclosed findings for LY-CoV555 monotherapy. Eli Lilly had also stated on Oct. 7th that it intended to seek an EUA in November for the combination therapy of its neutralizing antibody solutions.

(Source: Eli Lilly and Company Statement, 10/14/20; *New York Times*, Eli Lilly's antibody trial is paused over potential safety concern, 10/13/20)

Regeneron Pharmaceuticals, Inc. is seeking an EUA from the FDA for their monoclonal antibody cocktail (REGN-COV2) as a therapy to fight COVID-19. In a statement issued on Oct. 7th, the company said, [s]ubsequent to our discussions with regulatory authorities, we have submitted a request to the [FDA] for an

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COMPANY NEWS (continued from page 9)

[EUA] for our REGN-COV2 investigational antibody combination for COVID-19. Under our agreement with the U.S. government for the initial doses of REGN-COV2, if an EUA is granted the government has committed to making these doses available to the American people at no cost and would be responsible for their distribution. At this time, there are doses available for approximately 50,000 patients, and we expect to have doses available for 300,000 patients in total within the next few months Earlier this month, the company released preliminary data from a clinical trial and confirmed that President Trump had received a dose of the investigational antibody as part of his treatment following being diagnosed with COVID-19.

(Source: Regeneron Pharmaceuticals, Inc. Statement, 10/7/20)

Beckman Coulter received an EUA designation for its Access SARS-CoV-2 Immunoglobulin M (IgM) assay. "Since March, the Beckman Coulter team has worked around the clock to develop a suite of assays that play a critical role in the ongoing global fight against COVID-19," said Julie Sawyer Montgomery, president of Beckman Coulter in news release. "As a science-driven company, we continue in our commitment to deliver rigorously validated diagnostics of the highest quality that provide meaningful information, so doctors and patients alike can trust the results for urgent, care decisions."

(Source: Beckman Coulter, News Release, 10/9/20)

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

Oct. 27. **Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2020 (Virtual).** More information available here.

Nov. 16-18. **2020 ADRP Annual Conference (Virtual).** More details available here.

Nov. 17. **FDA Public Meeting – Communications About the Safety of Medical Devices (Virtual).** More details available here.

2021

Mar 8-10. **ABC Annual Meeting, Washington, D.C.** More details coming soon.

June 25-26. **64th Annual California Blood Bank Society Annual Meeting, Santa Clara, Calif.** More details coming soon.

May. 11-13. **2021 ADRP Conference**, **Kansas City, Mo.** More details coming soon.

Aug. 3-5. **ABC Medical Directors Workshop**, **Cleveland, Ohio.** More details coming soon.

Aug. 3-5. **ABC Summer Summit**, **Cleveland, Ohio.** More details coming soon.

Sept. 15-17. **4th European Conference on Donor Health and Management, Hamburg, Germany.** More details available here.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Components Manufacturing Manager (Bradenton, FL). SunCoast Blood Centers is accepting applications for a Components Manufacturing Manager to work at our Lakewood Ranch Head Quarters. This position manages and oversees component manufacturing activities and operations, and supervises Staff assigned to the department. Other Duties include: Assures that activities are conducted in compliance with SOPs and regulatory guidelines. Assists with the development and implementation of effective corrective action plans in response to non-compliance, deviations, or operational problems. Assists with the preparation and scheduling of periodic maintenance, calibration and validation of instruments and equipment and other duties as required to fulfill the organizations mission and vision. Qualified applications should possess an associate degree or equivalent experience. Prefer applicant to have MT or MLT licensure, but not required. Applicant must have four years component processing or other cGMP regulated environment, plus two years supervisory responsibility. To apply and view a complete Job Description of this position please visit https://www.scbb.org/careers.html. EOE. Applicant drug testing required.

Quality Assurance Specialist. The Quality Assurance Department at Hoxworth Blood Center provides regulatory, quality oversight for all processes at the Center. The position is responsible for conducting audits, quality assurance oversight and CLIA regulated laboratories processes. Assists with development of SOPs, data, report results, process and equipment validations, and compliance with applicable regulations. Ideal candidate will have experience with the following: 21 CFR Parts 210, 211, 600, 601, 606, 607, 610, 630, 640, 660, 42 CFR Part 493, ASHI standards, FACT standards, and AABB Standards. Have experience working in a clinical laboratory or FDA regulated environment; auditing experience; knowledge of histocompatibility testing; experience with quality management software and project management. Required Qualifications: Bachelor's degree with three (3) years experience; -OR-Associate's degree with five (5) years experience;-OR- seven (7) years experience. Degree and experience must be in a related field. Experience may require at least one (1) year supervision. Apply here – Requisition # 49502.

Med Techs (Schedule: Monday – Thursday, 12p noon – 10:30pm, with on-call rotation). We need YOUR laboratory knowledge to help save lives! Kentucky Blood Center is seeking a qualified medical technologist to perform and interpret serological procedures on specimens submitted for compatibility testing. This position also acts as an expert problem solver, and will resolve issues related to antibodies, blood typing, and cross-matching. The role regularly interacts with hospital laboratories, helping them find answers, and communicating findings. Qualifications: MT, MLS, CLS (4-year degree) with a minimum two years recent blood bank experience, required; ASCP is a plus. Must have strong verbal and written communication skills, and be proficient with MS Office, with the ability to navigate web applications, and custom systems. Reference Laboratory employees must exhibit great teamwork, a positive attitude, and a "Do What It Takes" work ethic, with the goal of helping our hospital customers and patients. Proof of education must be provided during the interview process. Benefits: Health/Dental/Vision/Life/Short Term Disability/Long Term Disability/Cancer Insurance/Accident Insurance/Flexible Spending Accounts/Health Savings Accounts/Paid Time Off/Paid Holidays/Employee Assistance Program/Retirement Savings Plan. For more info, and to apply, go to: https://kybloodcenter.org/aboutus/careers/.

Assistant/Associate Director Blood Transfusion Service (Massachusetts General Hospital, Harvard Medical School). The Blood Transfusion Service at the Massachusetts General Hospital seeks a full-time, early or mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology or hemostasis. Our service encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. We collaborate closely with clinical colleagues in bone marrow and solid organ transplantation, CAR-T cell therapy, cardiac surgery, trauma and critical care, neurology, and pediatrics. Service and teaching responsibilities will be shared with three other full and part-time staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatrics). Academic rank and salary will be based on experience and accomplishments. Please send a curriculum vitae and a description of interest to: Robert Makar, MD, PhD, GRJ148, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114-2696; or email to rmakar@mgh.harvard.edu. The Massachusetts General Hospital is an equal opportunity/affirmative action employer.