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Drug Combination for Treatment of COVID-19 Authorized

Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) to combine the two drugs, baricitinib and remdesivir, which are both FDA-approved, for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized adults and pediatric patients who are requiring supplemental oxygen. More information on this EUA is available in the authorization letter posted on the FDA website.

"Today's action demonstrates the FDA's steadfast efforts to make potential COVID-19 treatments available in a timely manner, where appropriate, while continuing to support research to further evaluate whether they are safe and effective," said FDA Commissioner Stephen M. Hahn, MD, in a press release, "As part of our Coronavirus Treatment Acceleration Program, the FDA continues to use every possible avenue to facilitate new treatments for patients as quickly as possible to combat COVID-19."

New FDA COVID-19 Diagnostic Test Resource Available to Health Care Providers

FDA published a new web page, *A Closer Look at Coronavirus Disease 2019 (COVID-19) Diagnostic Testing*. The web page is intended to support health care providers, other health professionals, and those who purchase COVID-19 tests by providing more technical information about the disease. Information about the different types of tests and FDA's efforts to increase access to testing is also listed.

Lead Smoking Cessation Efforts

A new resource highlighting the ways pharmacists are helping patients to stop using tobacco products has been developed by the American Pharmacists Association. The resource includes case studies demonstrating effective strategies for tobacco cessation, as well as a nine-minute video, designed for different audiences, that teaches how to use the resource and understand the cessation services pharmacists can help patients access.

PTCB Awards Over 1,000 Sterile Compounding Certifications

More than 1,000 Compounded Sterile Preparation Technician (CSPT) certifications have been granted by the Pharmacy Technician Certification Board (PTCB), since the program was launched three years ago. Increasingly, pharmacy technicians across the United States are assuming more advanced roles in different areas of pharmacy.

"Earning the CSPT credential demonstrates a technician's level of commitment to patient safety and provides an opportunity to be recognized for meeting rigorous CSPT requirements," said PTCB Executive Director and CEO William Schimmel, in a PTCB press release which also includes details on the requirements for the certification.

NABP and its member boards continue to explore the roles of pharmacy technicians and how they are expanding within the profession. In 2019, NABP held three task forces on this topic, which are summarized in the Task Force Reports section of the NABP website. In addition, NABP virtually hosted the Task Force on Pharmacy Technician Practice Responsibilities on September 1, 2020. The Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment will meet virtually on December 1, 2020, and will synthesize all of the previous task forces' recommendations into one consolidated report.

Happy Thanksgiving From NABP!

NABP wishes you and your loved ones a happy Thanksgiving!

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First COVID-19 Test for Self-Testing at Home Authorized

Food and Drug Administration (FDA) has authorized the first coronavirus disease 2019 (COVID-19) diagnostic test for self-testing at home through an emergency use authorization (EUA). The Lucira COVID-19 All-In-One Test Kit has been authorized for home use for individuals age 14 and older and suspected of COVID-19 by their health care providers, and is authorized for prescription use only. In addition, the test is authorized for use in point-of-care (POC) settings (eg, doctors' offices, hospitals, urgent care centers, and emergency rooms) for all ages, but samples must be collected by a health care provider when the test is used at the POC to test individuals younger than 14 years old.

FDA notes that while COVID-19 diagnostic tests have been authorized for at-home collection, this authorization is a significant step forward as this is the first test that can be fully self-administered and provide results at home. More information is available in a FDA news release.

HHS Partners With Pharmacies to Increase Access to Future COVID-19 Vaccines

The United States Department of Health and Human Services (HHS) is partnering with chain and independent community pharmacies to ensure maximized access to a COVID-19 vaccine when made available. The partnership covers about 60% of pharmacies throughout the 50 US states, District of Columbia, Puerto Rico, and the US Virgin Islands.

Pharmacy vaccinators are crucial public health partners for increasing the access of COVID-19 vaccines. Pharmacists and the technicians and interns working under their supervision are trained to provide immunizations in their communities. According to HHS, pharmacists are also a trusted health resource in their communities and have played a vital role in the public health response to COVID-19 by counseling patients, expanding access to childhood vaccinations during the pandemic, and ordering and administering COVID-19 tests.

authorized by FDA, the partnership is being established as a step forward in anticipation that one or more COVID-19 vaccines will be authorized or approved and recommended for use in the US before the end of 2020. NABP will keep its member boards of pharmacy updated on the COVID-19 vaccine as new information becomes available.

Monoclonal Antibody Authorized for Treatment of COVID-19

FDA has issued an EUA for the investigational monoclonal antibody therapy bamlanivimab for the treatment of mild-to-moderate COVID-19 symptoms in non-hospitalized adult and pediatric patients. While the investigational therapy is continuing to be evaluated for safety and effectiveness, bamlanivimab was shown to reduce COVID-19-related hospitalizations and visits to the emergency room for patients who are at high risk for disease progression.

The EUA requires that fact sheets that provide important information about using bamlanivimab in treating COVID-19 be made available to health care providers and to patients and caregivers, including dosing instructions, potential side effects, and drug interactions.

FDA Holding Public Workshop on Opioid REMS

FDA will be hosting a public workshop, "Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes – Exploring the Path Forward for Assessment," on December 11, 2020, from 9 AM – 5 PM EST.

Details, including the workshop objectives, are available on the FDA website. To assist in the workshop discussion, an issues paper is available that provides a brief overview of the Risk Evaluation and Mitigation Strategy (REMS) background and challenges with evaluating the REMS education intervention. Instructions for submitting electronic or written comments on this public workshop are available in the *Federal Register* notice. The deadline for comments is February 11, 2021.

World Antimicrobial Awareness Week Begins, Fight the Fakes Partners to Help Raise Awareness

The dangers of antimicrobial resistance and how substandard and falsified medicines contribute to its rising levels will be promoted as part of World Antimicrobial Awareness Week (WAAW) – November 18-November 24, 2020.

fake medicines, has partnered with one of its academic chapters, King's College London Fight the Fakes, to recognize World Health Organization's annual WAAW.

Throughout this week, several dedicated messages with corresponding videos recorded by King's College London Fight the Fakes will be posted to promote better use of antibiotics that can be shared through social media to help amplify the message.

Nationwide Recall of Metformin HCl Extended Release Tablets

Nostrum Laboratories, Inc is voluntarily recalling two lots of Metformin HCl Extended Release Tablets, USP 500 mg to the consumer level due to the product containing certain levels of nitrosamine impurities above the acceptable daily intake limit of 96 ng/day.

Nostrum Laboratories has been notifying its distributors nationwide and arranging the return for recalled products. Consumers are encouraged to consult with health care professionals to obtain replacements or seek other available treatment options. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program.

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