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# PROMETHEUS BIOSCIENCES LAUNCHES MONITR™ COVID-19 ASSISTANCE PROGRAM (M.C.A.P.)

The PROMETHEUS® Monitr™ Crohn's Disease Test is being offered through M.C.A.P., at no cost to qualifying patients\*

Prometheus' Monitr CD test, a noninvasive, serum-based test that can aid in the assessment of endoscopic disease activity in conjunction with other clinical findings

SAN DIEGO, CA – Prometheus Biosciences, Inc. ("Prometheus"), a biopharmaceutical company committed to the discovery, development, and commercialization of a broad portfolio of novel precision therapeutics and diagnostics for patients living with unmet needs in gastroenterology and autoimmune diseases, announced that it has launched the Monitr<sup>TM</sup> COVID-19 Assistance Program (M.C.A.P.) to provide adult Crohn's disease (CD) patients with access to this valuable test.

"During these unprecedented times, our focus at Prometheus continues to remain on the patients we serve. With the launch of M.C.A.P., we are providing qualifying adult CD patients impacted by COVID-19 with an effective disease-monitoring test at no cost," said Mark McKenna, President and CEO of Prometheus. "We believe that the adoption of this program by GI physicians could minimize the burden on Crohn's disease patients as the novel coronavirus continues to impact the global healthcare system. We are working on continued access to our mobile phlebotomy services to facilitate sample collection and mitigate the need for your patients to engage in any unnecessary travel."

As a direct result of the COVID-19 pandemic, many healthcare providers have canceled or may soon cancel elective outpatient colonoscopies that are used to assess the mucosal status of CD patients. As a result, physicians may need to make therapy decisions for patients with CD without the objective data provided by colonoscopy regarding disease activity. Prometheus' commercially-available Monitr test, a first-of-its kind, noninvasive serum test aids in distinguishing CD patients in endoscopic remission from those with active disease, enabling more informed treatment management decisions. The Monitr test has been validated, and results presented in Gastroenterology.

Maria T. Abreu, M.D., Director of the Crohn's

and Colitis Center, University of Miami Health System, commented, "As physicians who care for IBD patients, we want to make the best decisions about medications for our patients, especially in the face of COVID-19. Most of us have taken the measure to delay colonoscopies in our patients and we don't know when it will be safe to have patients return for colonoscopies. I am happy that our Crohn's patients can benefit from Monitr as a way of determining active disease or healed mucosa. Having patients avoid hospitals and laboratories all together is great during this special situation."

## About the Monitr COVID-19 Assistance Program (M.C.A.P.)

Prometheus Biosciences launched its Monitr COVID-19 Assistance Program to support patients with adult Crohn's disease. Through this assistance program, Prometheus is providing the Monitr test at no charge for those patients who have lost employment and/or commercial insurance coverage as a result of the COVID-19 outbreak.\* This program will be available to all qualifying patients from March 23, 2020 through June 1, 2020 where Prometheus Biosciences acts as the billing entity. For all other patients, Prometheus' existing financial assistance programs are still available. In addition, Prometheus is also working on continued, uninterrupted access to mobile phlebotomy services to facilitate sample collection and mitigate the need for patients to engage in any unnecessary travel. If you have any questions on how to order the Prometheus Monitr CD test, please contact Prometheus' client services team at 888-423-5227.

#### About Prometheus Biosciences, Inc.

Prometheus Biosciences, Inc., is a biopharmaceutical company committed to the discovery, development, and commercialization of a broad portfolio of novel precision therapeutics and diagnostics for patients living with unmet needs in gastroenterology and autoimmune diseases. Prometheus Biosciences, Inc., created through the June 2019 acquisition of Prometheus Laboratories by Precision IBD, is headquartered in San Diego, California.

#### For more information about Prometheus, please visit us at: prometheusbiosciences.com

\* Program will be available to all qualifying patients from March 23, 2020 through June 1, 2020 where Prometheus Biosciences acts as the billing entity.

# U.S. FOOD AND DRUG ADMINISTRATION APPROVES EPCLUSA® (SOFOSBUVIR/VELPATASVIR) FOR CHILDREN AGES 6 AND OLDER OR WEIGHING AT LEAST 17 KG WITH CHRONIC HEPATITIS C INFECTION

Pediatric approval of protease inhibitor-free, pangenotypic, pan-fibrotic, once-daily regimen supports HCV elimination efforts by providing critical option for broad range of populations

Foster City, CA—Gilead Sciences, Inc. (NASDAQ: GILD) announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental New Drug Application (sNDA) for Epclusa® (sofosbuvir 400mg/velpatasvir 100mg; sofosbuvir 200mg/velpatasvir 50 mg) for the treatment of people with chronic hepatitis C infection (HCV) as young as 6 years of age or weighing at least 17 kg, regardless of HCV genotype or liver disease severity. The recommended dosage of Epclusa in children ages 6 years and older is based on weight and liver function. Epclusa is the first pan-genotypic, protease inhibitor-free regimen approved in the United States for adults and children.

In the United States, there are approximately 23,000-46,000 children living with HCV. Children born to mothers with HCV are a growing concern, increasing in prevalence by 60 percent from 2011 to 2014. Additionally, engagement in high-risk practices, such as intravenous drug use, is an increasingly common route of HCV transmission in adolescents and young adults.

"While the treatment of HCV has been transformed in recent years, physicians caring for some children have still needed to take several factors into consideration, including genotype and liver disease severity, when selecting the appropriate treatment plan," said Kathleen B. Schwarz, MD, Professor of Pediatrics, Johns Hopkins University School of Medicine. "The expanded approval of Epclusa can help eligible children living with HCV combat this life-threatening and debilitating disease."

The approval of Epclusa is based on data from a Phase 2, open-label clinical trial (Study 1143) that enrolled 175 children who were treated with Epclusa for 12 weeks, of which 173 were included in the efficacy analysis. In children 12 to <18 years old, treatment with Epclusa resulted in a cure rate (SVR12) of 93 percent (71/76) in those with genotype 1 HCV infection and 100 percent in those with genotype 2 (6/6), genotype

3 (12/12), genotype 4 (2/2) and genotype 6 (6/6) HCV infection. In children 6 to <12 years old, the SVR rate was 93 percent (50/54) in those with genotype 1 HCV infection, 91 percent (10/11) in those with genotype 3 HCV infection, and 100 percent in those with genotype 2 (2/2) and genotype 4 (4/4) HCV infection. The safety profile of Epclusa in children 6 years of age and older treated was generally consistent with that observed in clinical trials in adults. The most common adverse reactions (incidence greater than or equal to 10 percent, all grades) observed with treatment with Epclusa for 12 weeks in adults are headache and fatigue.

"Gilead's continued commitment to HCV elimination includes bringing our medicines to the most difficult-to-cure populations and today's decision by the FDA represents an important step toward that goal," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "With consistently high cure rates in clinical trials and in the real world, Epclusa has the potential to help many of the children living with HCV in the United States."

For adults, Epclusa was first approved by the FDA and European Medicines Agency (EMA) in 2016. A line extension application for the use of Epclusa in children 6 to <18 years of age is currently under review with the EMA.

The U.S. product label for Epclusa contains a BOXED WARNING for the risk of hepatitis B reactivation in HCV/HBV co-infected patients. See below for U.S. Important Safety Information.

## IMPORTANT U.S. SAFETY INFORMATION AND INDICATION FOR THE USE OF EPCLUSA

## BOXED WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN HCV/HBV COINFECTED PATIENTS

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with EPCLUSA. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct acting antivirals (DAAs) and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Cases have been reported in patients who are HBsAg positive, in patients with serologic evidence of resolved HBV, and also in patients receiving certain immunosuppressant or chemotherapeutic agents; the risk of HBV

#### MEDICAL BULLETIN BOARD

reactivation associated with treatment with HCV DAAs may be increased in patients taking these other agents. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

#### **Contraindications**

If EPCLUSA is used in combination with ribavirin (RBV), all contraindications, warnings and precautions, in particular pregnancy avoidance, and adverse reactions to RBV also apply. Refer to RBV prescribing information.

#### Warnings and Precautions

Serious Symptomatic Bradycardia When Coadministered with Amiodarone: Amiodarone is not recommended for use with EPCLUSA due to the risk of symptomatic bradycardia, particularly in patients also taking beta blockers or with underlying cardiac comorbidities and/or with advanced liver disease. A fatal cardiac arrest was reported in a patient taking amiodarone who was coadministered a sofosbuvir containing regimen. In patients without alternative, viable treatment options, cardiac monitoring is recommended. Patients should seek immediate medical evaluation if they develop signs or symptoms of bradycardia.

Risk of Reduced Therapeutic Effect Due to Use with P-gp Inducers and/or Moderate to Potent Inducers of CYP2B6, CYP2C8 or CYP3A4: Rifampin, St. John's wort and carbamazepine are not recommended for use with EPCLUSA as they may significantly decrease sofosbuvir and/or velpatasvir plasma concentrations.

#### Adverse Reactions

The most common adverse reactions (≥10%, all grades) with EPCLUSA were headache and fatigue; and when used with RBV in decompensated cirrhotics were fatigue, anemia, nausea, headache, insomnia, and diarrhea.

#### Drug Interactions

Coadministration is not recommended with topotecan due to increased concentrations of topotecan; or with proton-pump inhibitors, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, efavirenz, and tipranavir/ritonavir due to decreased concentrations of sofosbuvir and/or velpatasvir.

Consult the full Prescribing Information for EPCLUSA for more information on potentially significant drug interactions, including clinical comments.

#### INDICATION

EPCLUSA is indicated for the treatment of adult and pediatric patients 6 years of age and older or weighing at least 17 kg with chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis and in combination with ribavirin for those with decompensated cirrhosis.

#### About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

#### Forward-Looking Statement

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors, including the risk that physicians may not see the benefits of prescribing Epclusa for the treatment of chronic HCV infection and the possibility of unfavorable results from ongoing and additional clinical studies involving Epclusa. Further, there is the possibility that the European Commission may not approve the line extension application for the use of Epclusa in the currently anticipated timelines or at all. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

(continued on page 46)

#### MEDICAL BULLETIN BOARD

(continued from page 44)

U.S. Prescribing Information for Epclusa, including BOXED WARNING, is available at www.gilead.com.

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For more information about Gilead, please visit the company's website at **gilead.com**, follow Gilead on Twitter (@Gilead Sciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

## SHERMAN PRIZE, INSPIRING EXCELLENCE IN CROHN'S AND COLITIS, NOW ACCEPTING NOMINATIONS

NAPLES, FL – The Bruce and Cynthia Sherman Charitable Foundation announced its annual call for nominations for the 2020 Sherman Prizes, recognizing exceptionally talented, dedicated individuals working tirelessly to improve outcomes for people with Crohn's disease and ulcerative colitis, and advancing research that could lead to prevention, remission, and cures.

Established in 2016, the Sherman Prize program is the first of its kind, providing financial prizes and national recognition to individuals who exemplify excellence in Crohn's disease and ulcerative colitis, also known as the inflammatory bowel diseases (IBDs).

"My wife Cynthia and I created the Sherman Prize to celebrate excellence in IBD and inspire greater advances so fewer families have to face the challenges of these diseases," said Bruce Sherman, Founder of the Sherman Prize. "It's been inspiring to see the innovative work being done by brilliant IBD professionals. We're excited to begin our fifth year and we can't wait to see who is nominated."

To date, twelve IBD professionals, representing diverse specialties, have been honored through the

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Prize program. They include physician scientists, a pediatric IBD specialist, a colorectal surgeon, a psychiatrist specializing in IBD and a physician assistant. To learn more about the many ways they are making life better for people with IBD, watch their tribute films at ShermanPrize.org.

Nominations for the 2020 Prizes may be submitted at **ShermanPrize.org** into the summer. A final deadline will be announced later in the spring. The Prizes will be presented December 10 at the Advances in IBD (AIBD) conference in Orlando, Florida.

#### About the Sherman Prize Program

The Sherman Prize program honors out-of-the-box thinkers from a variety of professional disciplines who represent "Excellence in Crohn's and Colitis" in their chosen endeavors, having dedicated their careers to the fight to overcome IBD.

Two \$100,000 Sherman Prizes are awarded annually to IBD clinicians, surgeons, researchers and/or academics, recognizing exceptional and pioneering contributions that transform the care of people with IBD. This Prize honors visionaries who are driven to solve IBD's most difficult challenges and whose work inspires future innovators.

A \$25,000 Sherman Emerging Leader Prize is awarded to an IBD clinician, surgeon, researcher, academic, physician assistant, nursing professional, or public health advocate who, while early in his or her career, has contributed to an advancement and shows great promise for significant future contributions.

Sherman Prize honorees are selected by the Sherman Prize Board of Directors, with guidance from the Sherman Prize Selection Committee, chaired by Dr. Dermot P.B. McGovern, the Joshua L. and Lisa Z. Greer Endowed Chair in Inflammatory Bowel Disease Genetics at Cedars-Sinai. Joining him on the Selection Committee are Dr. Lee Denson, Cincinnati Children's Hospital Medical Center; Dr. Mark Gerich, University of Colorado Crohn's and Colitis Center; Dr. Sunanda Kane, Mayo Clinic; and Dr. Amy Lightner, Cleveland Clinic.

Full eligibility guidelines and guidance on how to submit a nomination may be found at:

ShermanPrize.org