NVHR Welcomes Two Federal Actions to Help Prevent and Treat Hepatitis B

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CDC Recommended HEPLISAV-B Vaccine to Prevent Hepatitis B in Adults; FDA Granted Orphan Drug Designation to Tenofovir Exalidex (TXL) to Treat the Virus in Children

SAN FRANCISCO, CA (March 5, 2018) – The National Viral Hepatitis Roundtable (NVHR), a national coalition working together to eliminate hepatitis B and hepatitis C in the United States, today welcomed recent action by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) to prevent and treat hepatitis B. Last week, the CDC Advisory Committee on Immunization Practices (ACIP) recommended HEPISLAV-B – which became the first hepatitis B vaccine approved in the United States in more than 25 years when it was licensed by the FDA in November 2017 – to vaccinate adults against hepatitis B. Also last week, the FDA granted Orphan Drug Designation to tenofovir exalidex (TXL) to help fast-track the treatment of hepatitis B in pediatric patients (ages 0-11 years old).

“Results-driven federal action is needed to stem the tide of hepatitis B infections in the U.S.,” said Dr. Robert Gish, NVHR Executive Committee Vice Chair. “The CDC’s recommendation of HEPLISAV-B and the FDA’s Orphan Drug Designation of TXL represent a significant step forward for patients living with hepatitis B. We look forward to working with our advocacy partners to ensure widespread access to this revolutionary vaccine among adults and to this novel treatment for infected children.”

Hepatitis B is an extremely infectious and potentially deadly virus affecting up to 2 million people in the United States. Asian Americans and Pacific Islanders are disproportionately impacted, accounting for more than 50 percent of people living with chronic hepatitis B in the country. While there is effective treatment for hepatitis B, there is no cure and infections are on the rise. In 2015, new cases of acute hepatitis B increased by more than 20 percent, largely as a result of the nation’s opioid crisis.

In March 2017, the National Academies of Sciences, Medicine and Engineering released A National Strategy for the Elimination of Hepatitis B and C. The National Academies noted that only a quarter of adults over the age of 19 have been fully immunized against hepatitis B and called for expanded access to vaccination as part of the overall strategy to eliminate the public health threat of hepatitis B in the United States by 2030. Approved by the FDA on November 9, 2017, HEPLISAV-B is the first new hepatitis B vaccine licensed in the U.S. in more than 25 years. Previous hepatitis B vaccines required three shots over a six-month period for full protection; however, almost half of adults failed to complete the series within one year. HEPLISAV-B is a two-dose vaccination taken over a one-month period, increasing the likelihood of successful completion.

Hepatitis B infection rates remain high among children who are infected at birth or in early childhood. Current pediatric (and adult) treatment options are generally lifelong, painful, and ineffective. In contrast, TXL is a novel hepatitis B treatment with few side effects and has potential to become part of a curative combination therapy for the virus. On February 21, 2018, the FDA granted TXL Orphan Drug Designation, which qualifies the treatment for seven years of market exclusivity in the U.S. upon

approval, financial assistance in clinical research and development, and an accelerated evaluation of the registration package by the FDA.

“The National Academies report confirms that hepatitis B elimination is within reach,” Tina Broder, NVHR Interim Executive Director. “We encourage the federal government to continue to take steps to ensure that all at-risk Americans get vaccinated for hepatitis B and to connect those living with the virus with the best treatments available.”

About the National Viral Hepatitis Roundtable (NVHR)
The National Viral Hepatitis Roundtable is a national coalition working together to eliminate hepatitis B and hepatitis C in the United States. Our vision a healthier world without hepatitis B and hepatitis C. For more information, visit www.nvhr.org.

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