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Janssen Announces Exclusive, Worldwide License Agreement with Arrowhead Pharmaceuticals to Develop and Commercialize a New Treatment for Chronic Hepatitis B Viral Infection

Agreement expands breadth of Janssen's hepatitis B virus development portfolio

TITUSVILLE, N.J., October 4, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that Janssen Pharmaceuticals, Inc., (Janssen) has entered into an agreement with Arrowhead Pharmaceuticals, Inc., (Arrowhead) for an exclusive, worldwide license to develop and commercialize ARO-HBV, a Phase 1/2 subcutaneous, ribonucleic acid interference (RNAi) therapy candidate being investigated for the treatment of chronic hepatitis B viral infection.

Under the agreement, Arrowhead will complete the ongoing Phase 1/2 clinical trial for ARO-HBV, a next-generation RNAi therapy candidate which is designed to silence HBV gene products by specifically targeting two regions of the HBV genome. Janssen will lead the clinical development from Phase 2b onwards. Arrowhead will receive an initial upfront payment, potential development and commercial milestone payments and potential future royalties. Separately, Johnson & Johnson Innovation – JJDC, Inc., will make an equity investment in Arrowhead.

Janssen and Arrowhead also agreed to a research collaboration to develop RNAi therapeutics directed against additional targets using Arrowhead's proprietary Targeted RNAi Molecule (TRiM™) platform. If Janssen exercises its option for such RNAi therapeutics, Arrowhead will be eligible to receive additional payments.

Hepatitis B viral infection presents a major global health concern and places a significant burden on the 257 million people living with the disease worldwide.[1,2] While a prophylactic vaccine for hepatitis B exists, many people living with chronic hepatitis B remain uncured by current treatments and endure lifelong therapy.[1] RNAi therapy candidates such as ARO-HBV have been shown to have an effect on hepatitis B viral infection replication pathways and on the production of viral proteins, providing another avenue for investigation into treatments in this area.[3]

"An important objective within Janssen is to develop highly effective combination products that cure people living with chronic hepatitis B infections," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC. "Working with the talented Arrowhead team and their RNAi therapy candidate adds to the strength of our hepatitis B portfolio and substantially increases our confidence that we can achieve our objective."

The transactions are subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act and expected to close in Q4 2018.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com and follow us at @JanssenGlobal. Janssen Pharmaceuticals, Inc. and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

About Johnson & Johnson Innovation – JJDC, Inc.

Johnson & Johnson Innovation – JJDC, Inc. (JJDC) is the strategic venture capital arm of Johnson & Johnson and a long-term investment partner to global healthcare entrepreneurs. Founded in 1973, JJDC continues a legacy of customizing deals for data-driven companies across the continuum of healthcare, with the goal of turning great ideas into transformative new pharmaceutical, medical device and consumer healthcare products. Visit our website at www.jjdc.com.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding a new license and collaboration agreement and the continued development of potential treatment regimens for hepatitis B. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Pharmaceuticals, Inc., Johnson & Johnson Innovation – JJDC, Inc., any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges and uncertainties inherent in product development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new indications and therapeutic combinations; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behaviour and spending patterns or financial distress of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the year ended December 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

References

1. World Health Organization (WHO). Hepatitis B. July 2017. Available at: http://www.who.int/mediacentre/factsheets/fs204/en/ Last accessed September 2018.
2. World Health Organization (WHO). Draft global health sector strategy on viral hepatitis, 2016-2021 Sixty-ninth World Health Assembly provisional agenda item 15.1. Document A69/32. April 2016. Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_32-en.pdf?ua=1 Last accessed September 2018.

3. Yuen MF *et. al.,* RNA interference therapy with ARC-520 Injection results in long term off-therapy antigen reductions in treatment naïve, HBeAg positive and negative patients with chronic HBV. Poster FRI-362 presented at EASL 2018, April 13, 2018 [LINK].