



Arrowhead Collaborator Janssen Begins REEF-1 Phase 2b Combination Study in Patients with Chronic Hepatitis B Infection

August 28, 2019

- Arrowhead earns \$25 million milestone payment in connection with trial initiation

PASADENA, Calif.--(BUSINESS WIRE)--Aug. 28, 2019-- Arrowhead Pharmaceuticals Inc. (NASDAQ: ARWR) today announced that Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, has begun dosing in a Phase 2b study (REEF-1) of different combination regimens, including JNJ-3989 (formerly ARO-HBV), and/or JNJ-6379, and a nucleos(t)ide analog (NA) for the treatment of chronic hepatitis B virus infection. In connection with the start of this study, Arrowhead earned a \$25 million milestone payment from Janssen.

JNJ-3989 is a liver-targeted investigational antiviral therapeutic for subcutaneous injection designed to treat chronic HBV infection via the ribonucleic acid interference (RNAi) mechanism. JNJ-6379 is an investigational orally administered capsid assembly modulator of the class that forms normal capsid structures (CAM-N). Arrowhead entered into a license and collaboration agreement with Janssen in October 2018 to develop and commercialize ARO-HBV.

Christopher Anzalone, Ph.D., president and chief executive officer at Arrowhead, said: "Patients with chronic hepatitis B infection are in need of new medicines that improve functional cure rates with finite treatment regimens. We are thrilled that JNJ-3989, formerly ARO-HBV, is one of the agents being investigated in Janssen's REEF-1 triple combination Phase 2b study."

REEF-1 ([NCT03982186](#)) is a Phase 2b, multicenter, double-blind, active-controlled, randomized study to investigate the efficacy and safety of different combination regimens, including JNJ-3989, JNJ-6379, NA, and/or placebo in patients with chronic hepatitis B virus infection. The study is planned to include up to 450 patients who will be randomized to receive up to 48 weeks of treatment.

Hepatitis B infection is a life-threatening viral infection of the liver, which can cause cirrhosis — scarring of liver tissue — and liver cancer after prolonged period of chronic infection. The World Health Organization cites that hepatitis B is a global public health problem affecting 292 million people worldwide.¹ While a preventive vaccine is available, cure rates for those infected remain low and most patients will endure lifelong therapy.

About Arrowhead Pharmaceuticals

Arrowhead Pharmaceuticals develops medicines that treat intractable diseases by silencing the genes that cause them. Using a broad portfolio of RNA chemistries and efficient modes of delivery, Arrowhead therapies trigger the RNA interference mechanism to induce rapid, deep, and durable knockdown of target genes. RNA interference, or RNAi, is a mechanism present in living cells that inhibits the expression of a specific gene, thereby affecting the production of a specific protein. Arrowhead's RNAi-based therapeutics leverage this natural pathway of gene silencing.

For more information, please visit www.arrowheadpharma.com, or follow us on Twitter [@ArrowheadPharma](#). To be added to the Company's email list and receive news directly, please visit <http://ir.arrowheadpharma.com/email-alerts>.

Safe Harbor Statement under the Private Securities Litigation Reform Act:

This news release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements are based upon our current expectations and speak only as of the date hereof. Our actual results may differ materially and adversely from those expressed in any forward-looking statements as a result of various factors and uncertainties, including the safety and efficacy of our product candidates, the duration and impact of regulatory delays in our clinical programs, our ability to finance our operations, the likelihood and timing of the receipt of future milestone and licensing fees, the future success of our scientific studies, our ability to successfully develop and commercialize drug candidates, the timing for starting and completing clinical trials, rapid technological change in our markets, and the enforcement of our intellectual property rights. Our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q discuss some of the important risk factors that may affect our business, results of operations and financial condition. We assume no obligation to update or revise forward-looking statements to reflect new events or circumstances.

Source: Arrowhead Pharmaceuticals, Inc.

¹ The Polaris Observatory Conservatory. Global prevalence, treatment, and prevention of hepatitis B. The Lancet Gastroenterology & Hepatology. VOLUME 3, ISSUE 6, P383-403, JUNE 01, 2018

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