# Arrowhead and Collaborator Janssen Present Phase 2 Clinical Data on Investigational Hepatitis B Therapeutic JNJ-3989 at The Digital Liver Congress

August 28, 2020

PASADENA, Calif.--(BUSINESS WIRE)--Aug. 28, 2020-- Arrowhead Pharmaceuticals Inc. (NASDAQ: ARWR) today announced the presentation of Phase 2 clinical data from the AROHBV1001 phase 1/2 study on a double combination of JNJ-3989 (formerly ARO-HBV) and a nucleos(t)ide analog (NA) with collaborator Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson. The data are being presented in an oral presentation at The Digital International Liver Congress - The Annual Meeting of the European Association for the Study of the Liver (EASL).

JNJ-3989 is a liver-targeted investigational antiviral therapeutic for subcutaneous injection designed to treat chronic HBV (CHB) infection via the ribonucleic acid interference (RNAi) mechanism.

Janssen is currently conducting 48-week phase 2b studies of JNJ-3989 + NA, with or without JNJ-6379 to assess functional cure rates in patients with CHB. 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 JNJ-3989.

**Presentation Details:**

- Title: **Short-term treatment with RNA interference therapy, JNJ-3989, results in sustained hepatitis B surface antigen suppression in patients with chronic hepatitis B receiving nucleos(t)ide analogue treatment**
- Authors: Edward Gane, *et al.*
- Type: Oral Presentation
- Date and Time: August 28, 2020 at 13:30 CEST

Key points presented include the following:

- In the AROHBV1001 study in CHB patients, JNJ-3989 was administered on Days 0, 28, and 56 in combination with daily oral NA treatment
    - The objectives of this analysis were to assess sustained response in hepatitis B surface antigen (HBsAg), HBV RNA, hepatitis B e-antigen (HBeAg) and hepatitis B core-related antigen (HBcrAg) up to Day 392, 48 weeks after the last JNJ-3989 dose in patients with CHB continuing with NA treatment from Day 0 to end of study
        - Sustained responders were classified as those CHB patients with ≥1 log10 IU/mL reduction in HBsAg from Day 0 to Day 392
- For the first time in patients with CHB, siRNA therapy resulted in sustained, off-treatment ≥1log10 IU/mL reductions in HBsAg through to 48 weeks in 39% of patients after the last JNJ-3989 dose
- Reductions in HBV RNA, HBeAg, HBcrAg were seen across all cohorts, and were more pronounced in HBsAg sustained responders than non-responders
- Three injections of JNJ-3989 administered once every 4 weeks were well tolerated at doses up to 400 mg and appeared to have a good long-term safety profile
- These results support the evaluation of longer durations of treatment with JNJ-3989 + NA, with the objective of providing a functional cure in patients with CHB

A copy of the presentation materials may be accessed on the Events and Presentations page under the Investors section of the Arrowhead website.

**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.

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