



NEWS RELEASE

New Data Published In The New England Journal Of Medicine Shows Potential Of Compound To Fight RSV Infection In Adults And Children

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South San Francisco, United States, November 18 2015 - Alios BioPharma, Inc., part of the Janssen Pharmaceutical Companies announced that the New England Journal of Medicine (NEJM) will publish findings from a respiratory syncytial virus (RSV) challenge study for ALS-008176, a cytidine nucleoside analog with activity against RSV. Among infants and young children, RSV is the leading cause of severe respiratory illness and remains the most frequent cause of hospitalization in industrialized countries.³ This Phase 2a study has now established human proof-of-concept for the antiviral activity of ALS-008176 in healthy adults and highlights its potential as a therapy for managing clinical disease in naturally infected patients¹.

"The data suggest that ALS-008176 has the potential to be a safe and effective treatment for RSV infection. The primary endpoint of the study was met and ALS-008176 significantly reduced viral load and symptoms of disease severity compared to placebo," said John DeVincenzo, M.D., the lead study author and Professor of Pediatrics, and Professor of Microbiology, Immunology and Biochemistry at the University of Tennessee Health Science Center, and Medical Director of Molecular and Viral Diagnostics at Le Bonheur Children's Hospital. "ALS-008176 can inhibit the replication of RSV even if the cells of the respiratory tract have already been infected with the virus. As a result, this treatment has an antiviral effect and is likely to be effective even if started at a later stage of RSV infection."

In this randomized, double-blind study, 62 healthy volunteers were inoculated with RSV and subsequently randomized to receive ALS-008176 or placebo. Compared to placebo, treatment with ALS-008176 resulted in a significant reduction of viral load (73-88% reduction in viral load area under the curve) and faster viral clearance

(1.3-2.3 days vs 7.2 days) versus placebo. At the time that the peak viral load occurred in the placebo group, the mean viral load in each of the three ALS-007186 treatment groups was more than one thousand times lower. In addition, statistically significant reductions in symptom scores and a reduction of the amount of congesting respiratory secretions were also observed.

In the study, no serious adverse events (SAEs), premature discontinuations of study drug, or clinically significant treatment related adverse events (AEs) were observed. The most commonly reported AEs were epistaxis (bleeding from the nose), upper respiratory infection and cough. AEs were generally balanced in terms of frequency and intensity across recipients of ALS-008176 and placebo. ALS-008176 also demonstrated a high barrier to resistance. No participants receiving ALS-008176 experienced viral rebound or had evidence of viral resistance during the course of the study.¹

RSV is a seasonal virus that affects the lungs and airways for which there is currently no vaccine and no guideline-recommended antiviral treatment options available. RSV can be partially prevented by a monoclonal antibody, but its use is limited to a small fraction of premature infants or infants with uncommon heart or lung problems.^{2,3} Each year, there are approximately 64 million cases of RSV infection among adults and children and nearly 100% of infants will have at least one RSV infection by their second year of life.⁴ In a single year (2005), around 33.8 million infants and young children had RSV infections in the lower respiratory tract and at least 3.4 million were hospitalized. This was associated with between 66,000 and 199,000 deaths.⁵

"Janssen is currently working on the discovery and development of multiple treatment and vaccine candidates against RSV infection," said Lawrence M. Blatt, PhD, Global Therapeutic Area Head Infectious Diseases and Vaccines, Janssen Research & Development, LLC. "The data published in the New England Journal of Medicine highlight the potential this new compound has to effectively treat patients suffering from severe RSV infection. It underscores our commitment to develop highly innovative healthcare solutions in areas of great unmet need."

ALS-008176 is an orally bioavailable prodrug of the RSV replication inhibitor ALS-008112, a cytidine nucleoside analog. It is designed to inhibit the replication of RSV by acting on the viral polymerase and is currently being evaluated in hospitalized RSV-infected infants.

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About the Janssen Pharmaceutical Companies

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Alios BioPharma Inc., and Janssen Research & Development, LCC are part of

the Janssen Pharmaceutical Companies. Please visit <http://www.janssen.com> for more information.

About Janssen's Development Programs in Respiratory Diseases

Janssen is dedicated to the ongoing research and development of innovative solutions which will help to prevent and treat severe respiratory infections including influenza and human respiratory syncytial virus (RSV), with the goal of reducing worldwide burden. Janssen is currently working on the discovery and development of multiple treatment and vaccine candidates against influenza and RSV.

Within **RSV**, our development program includes the cytidine nucleoside analog inhibitor ALS-008176. This compound is currently being evaluated in clinical studies in the hospital setting. We also have an investigational fusion inhibitor which is currently undergoing a Phase 2a human challenge study and an RSV vaccine candidate Ad35.RSV.FA2 which has entered a Phase 1 study in the U.S to evaluate the safety, tolerability and immunogenicity in healthy adults.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. 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 Alios BioPharma, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including uncertainty of clinical success and obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 fiscal year ended December 28, 2014, including in Exhibit 99 thereto, 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.

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¹DeVincenzo JP, et al. Activity of Oral ALS-008176 in a Respiratory Syncytial Virus Challenge Study. *New England Journal of Medicine*. 19 November 2015.

²Centers for Disease Control and Prevention. Respiratory Syncytial Virus Infection (RSV): For Healthcare Professionals [Online]. Available at: <http://www.cdc.gov/rsv/clinical/> Last accessed October 2015.

³American Academy of Pediatrics Committee on Infectious Diseases, American Academy of Pediatrics Bronchiolitis

Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics* 2014;134:415-20.

⁴World Health Organization. Initiative for Vaccine Research: Acute Respiratory Infections [Online]. Available at: http://apps.who.int/vaccine_research/diseases/ari/en/index2.html Last accessed October 2015.

⁵Nair H, et al. Global burden of acute lower respiratory infections due to respiratory syncytial virus in young children: a systematic review and meta-analysis. *Lancet*. 2010;375:1545-55.

Media Contact: Daniel De Schryver (Global)

Mobile: +49 173 76 89 149

Email: ddschryv@its.jnj.com