MEDIA CONTACT:
Rebecca Genin
+1 215-620-8721
Rgenin1@its.jnj.com

Kristina Chang
+1 201-213-4115
Kchang12@its.jnj.com

INVESTOR RELATIONS:
Lesley Fishman
+1 732-524-3922

Joseph J. Wolk
+1 732-524-1142

Janssen Announces Pivotal Phase 3 Study Results for Investigational Darunavir-Based Single-Tablet Regimen for the Treatment of HIV-1 Infection in Adults Switching from Boosted Protease Inhibitors Plus Emtricitabine and Tenofovir Disoproxil Fumarate Regimens

EMERALD 48-week safety and efficacy results
published in The Lancet HIV and to be presented at IDWeek

SAN DIEGO, OCTOBER 6, 2017 – Janssen Pharmaceutica, NV announced results from the pivotal Phase 3 EMERALD study which were published today online in *The Lancet HIV* and will be presented at IDWeek 2017 in San Diego. The study met its primary endpoint, which focused on virologic rebound rate, and demonstrated that switching to the investigational single-tablet regimen (STR) containing darunavir 800 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg (D/C/F/TAF) was non-inferior to continuing treatment with a boosted protease inhibitor (PI) plus emtricitabine and tenofovir disoproxil fumarate in human immunodeficiency virus type 1 (HIV-1) positive, virologically suppressed adults. There were no observed resistance associated mutations (RAMs) to study drugs through 48 weeks. If approved in the U.S., D/C/F/TAF would be the only complete regimen that may deliver the potential adherence benefit of a once-daily STR with the durability and high genetic barrier to resistance of darunavir and the demonstrated bone and renal safety profile of TAF.

"When people who are diagnosed with HIV don't adhere to their treatment regimen, they can build up drug resistance, which can render their treatment – and even an entire class of treatments – ineffective," said Joseph Eron, MD, Professor of Medicine and Director, Clinical Core, University of North Carolina Center for AIDS Research, Chapel Hill, NC. "The findings from the EMERALD study bring us one step closer to being able to offer those who live with HIV and struggle with adherence an option that combines the

efficacy and high genetic barrier to resistance of darunavir with the demonstrated safety profile of tenofovir alafenamide into a single tablet."

About the EMERALD clinical trial

The Phase 3 EMERALD study is a randomized (2:1), open-label, international, multi-center, parallel-group, non-inferiority, 48-week study evaluating the efficacy and safety of switching to D/C/F/TAF versus continuing with a boosted PI (lopinavir/ritonavir, atazanavir or darunavir boosted by either ritonavir or cobicistat) plus emtricitabine/tenofovir disoproxil fumarate in adult HIV-1 infected patients who are virologically suppressed (viral load [VL] <50c/mL for ≥2 months and had no more than one VL ≥50c/mL and <200 c/mL allowed within 12 months before screening). The FDA-stipulated primary endpoint of the trial is the proportion of patients with virologic rebound (confirmed VL≥50c/mL or premature discontinuations with last VL≥50c/mL) cumulative through week 48 (non-inferiority margin=4%). 1,141 patients were randomized and treated as follows: D/C/F/TAF (n=763); control (n=378). Inclusion criteria to be enrolled in the trial included absence of history of virologic failure on darunavir, and if historical genotype was available, absence of darunavir RAMs.

Through 48 weeks, cumulative virologic rebound was 2.5% (D/C/F/TAF, n=19) vs. 2.1% (control, n=8) with 12/19 in D/C/F/TAF and 4/8 in the control group re-suppressed (<50 c/mL) by the end of the evaluation period. Additionally, at week 48, virologic suppression was 94.9% (D/C/F/TAF) and 93.7% (control), and virologic failure occurred in 0.8% and 0.5%, respectively, with no discontinuations for virologic failure and no observed RAMs to any study drug through 48 weeks.

D/C/F/TAF also demonstrated similar safety versus control group through 48 weeks. Rates of discontinuations due to adverse events (AEs) were 1.4% (D/C/F/TAF) vs. 1.3% (control); Grade 3-4 AEs were 6.8% (D/C/F/TAF) vs. 8.2% (control); and serious AEs were 4.6% (D/C/F/TAF) vs. 4.8% (control). There were no deaths in either arm of the study. The most common AEs were nasopharyngitis (D/C/F/TAF 10.6% vs. control 10.3%), upper respiratory tract infection (10.6% vs. 10.3%), and diarrhea (7.9% vs. 4.2%).

"At Janssen, we are committed to developing a broad range of therapies to meet the diverse needs of the HIV community," said Magda Opsomer, MD, Senior Director, Clinical Leader, Janssen Infectious Diseases. "Today, stigma, lifestyle and pill burden continue to create adherence challenges for many people living with HIV. If approved, the darunavir STR would be an important option that may help address these adherence barriers by

offering a once daily, single-pill dosing regimen with the high genetic barrier to resistance of darunavir."

On September 25, 2017, the European Commission approved the use of D/C/F/TAF for the treatment of HIV-1 infection in adults and adolescents aged 12 years and older with body weight of at least 40 kg. This approval allows Janssen to market D/C/F/TAF in all member states of the European Union and the European Economic Area. In the U.S., D/C/F/TAF is an investigational product. A new drug application (NDA) was filed on September 22, 2017 to the U.S. Food and Drug Administration (FDA), and is currently awaiting approval. The NDA was filed for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older and was based on the results from two pivotal Phase 3 studies, EMERALD and AMBER. AMBER is a 48-week, double-blind, non-inferiority study evaluating the efficacy and safety of D/C/F/TAF in antiretroviral therapy (ART) treatment-naïve patients. Phase 3 AMBER data through 48 weeks will be presented at the upcoming European AIDS Conference, October 25-27, 2017 in Milan, Italy.

To learn more about Janssen's commitment to the prevention and treatment of HIV, please visit jnj.com/HIV.

###

Notes to editors

Cobicistat, emtricitabine and tenofovir alafenamide are from Gilead Sciences, Inc. On December 23, 2014, Janssen and Gilead Sciences Inc. amended a licensing agreement for the development and commercialization of a once-daily STR combination of darunavir and Gilead's TAF, emtricitabine and cobicistat. Under the terms of the agreement, Janssen and its affiliates are responsible for the manufacturing, registration, distribution and commercialization of this STR worldwide.

For more information on the clinical trials please visit: www.clinicaltrials.gov

About Janssen

At Janssen, 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. Follow us at www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the advantages and potential approval of a new treatment option for HIV-1. 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 Pharmaceutica NV, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; 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 January 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including under the caption "Cautionary Note Regarding Forward-Looking Statements," 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.

###