



Janssen Identifies Trace Amounts of TBA in 5 Batches of PREZISTA[®]▼ (darunavir) in the EU and Canada

The Company is Working With Regulatory Authorities

High Wycombe, UK - 11 May 2011 - Janssen-Cilag International N.V. today announced the company is working with regulatory authorities in five countries to address trace amounts of TBA (2,4,6 tribromoanisole) identified in five batches of the HIV/AIDS medicine PREZISTA[®]▼ (darunavir). The countries affected include the United Kingdom, Ireland, Germany, Austria and Canada.

Janssen initiated discussions with regulatory authorities after receiving four consumer reports of an uncharacteristic ("musty, mouldy") odour. The company's investigation determined that the odour is likely caused by trace amounts of TBA found in bottles sourced from a common supplier. As discussions with regulatory authorities in each of the five countries continue, the company is committed to recalling and replacing any affected bottles of product remaining in the marketplace - estimated to be fewer than 2,000 in total in countries where recalls have been initiated.

Company discussions with the European Medicines Agency resulted in agreement on a Class II recall at the wholesale and retail (pharmacy) level. Discussions with regulatory authorities in Canada are underway to determine the appropriate course of action. The Company does not anticipate a product shortage resulting from the company's actions to recall and replace affected product.

Patients should not stop taking their medication. Anyone experiencing an uncharacteristic odour associated with PREZISTA[®]▼ 400mg or 600mg Tablets - or anyone with questions about the company's actions to recall and replace - should contact the company at 0800 032 3013 (freephone).

It should be noted that in the UK PREZISTA[®]▼ 400mg is only affected. PREZISTA[®]▼ 75mg, 150mg and 300mg are not subject to this action.

Listed below are the five affected batches of PREZISTA[®]▼ 400mg and 600 mg Tablets:

Package Description	Product Code	Lot Number	Expiry	Country
PREZISTA [®] ▼ (darunavir) film-coated TABLETS 400mg Bottles of 60 Tablets	386333	AKZ0B00	October 2012	Germany, Austria
	386471	AFZ0C00	May 2012	United Kingdom, Ireland
PREZISTA [®] ▼ (darunavir) film-coated TABLETS 600mg Bottles of 60 Tablets	386332	ALZ0E00	October 2012	Germany, Austria
		AKZ0D00	October 2012	Germany
PREZISTA [®] ▼ (darunavir) film-coated TABLETS 600mg Bottles of 60 Tablets	62058	ALZ0J00	November 2012	Canada

TBA is a byproduct of a chemical preservative sometimes applied to wood often used in the construction of pallets on which products are transported and stored. While not considered to be toxic, TBA can generate an offensive odour and a very small number of patients have reported temporary gastrointestinal symptoms. As it relates to PREZISTA[®]▼, there have been no reported serious adverse events caused by the presence of TBA.

In January 2010, Janssen instituted a number of actions to reduce the potential of TBA contamination, including requiring

suppliers to verify that they do not use pallets made from chemically-treated wood. An internal investigation is underway with suppliers to evaluate all potential sources of TBA. In addition, Janssen is working with peer companies to better understand how and where TBA is entering and impacting the supply chains and what it can do to further mitigate this exposure.

About Janssen

Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving important unmet medical needs, including oncology (e.g. multiple myeloma and prostate cancer), immunology (e.g. psoriasis), neuroscience (e.g. schizophrenia, dementia and pain), infectious disease (e.g. HIV/AIDS, Hepatitis C and tuberculosis), and cardiovascular and metabolic diseases (e.g. diabetes).

Driven by our commitment to patients, we develop sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, based on partnerships of trust and transparency.

About PREZISTA[®]▼ (darunavir)

For treatment-experienced adult patients, including those that have been highly pre-treated, the licensed dosing for PREZISTA[®]▼ (darunavir) is 600 mg taken with 100 mg ritonavir twice daily with food or 800 mg taken with 100 mg ritonavir once-daily with food for treatment-experienced adult patients with no DRV RAMs¹ and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≤ 100 cells x 10⁶/L. For treatment-naive adult patients, the licensed dosing for darunavir is 800 mg taken with 100 mg ritonavir once-daily with food. Darunavir must be taken in combination with other antiretroviral agents. Darunavir/ritonavir is also indicated for use in HIV-1 infected treatment-experienced children aged 6 to 18 years old and at least 20kg in body weight.

PREZISTA[®]▼ 400mg tablets are light orange and are embossed with "TMC" on one side and "400MG" on the other.

PREZISTA[®]▼ 600mg tablets are orange and are embossed with "TMC" on one side and "600MG" on the other .

Important Safety Information

In the registrational studies, darunavir was generally well tolerated. The majority of the adverse reactions reported in patients who initiated therapy with darunavir co-administered with 100 mg ritonavir were mild to moderate in severity. The most frequent adverse reactions reported in clinical trials and as spontaneous reports are diarrhoea, immune reconstitution syndrome, nausea, pyrexia and rash. The most frequent serious reactions are diarrhoea, hepatitis, immune reconstitution syndrome, pyrexia and rash. Please see the summary of product characteristics for a complete list of all possible side effects.

Before taking darunavir, patients should tell their doctor if they have any medical conditions, including liver problems, including hepatitis B or C, diabetes, symptoms of infections, change in body fat, haemophilia, musculoskeletal problems, or allergy to sulfa medicines and should tell their doctor if they are pregnant or planning to become pregnant, or are nursing.

Darunavir should not be used in patients allergic (hypersensitive) to darunavir or ritonavir or with severe liver problems.

Due to potential drug interactions, patients should talk to their healthcare provider about all the medicines they are taking or plan to take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Darunavir does not cure HIV infection or AIDS, and does not prevent passing HIV to others. Please see full Summary of Product Characteristics for more details.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995.

These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; trends toward health care cost containment; and increased scrutiny of the healthcare industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 2, 2011. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Janssen-Cilag International NV nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.

¹V11I, V32I, L33F, I47V, I50V, I54L/M, T74P, L76V, I84V, L89V