



Sanofi Launches New Priftin® (Rifapentine) Packaging

New 24 and 32-Packs Designed to Manage Dosage Regimens for both Latent and Active Tuberculosis

Bridgewater, NJ – December 1, 2015 - Sanofi announced today the launch of a new 24-count tablet pack of Priftin® (rifapentine) for the treatment of latent tuberculosis infection (LTBI) in patients two years of age and older who are at high risk of progression to tuberculosis (TB) disease. The new 24-count package is tailored for use in the treatment of LTBI and represents one month of Priftin for most patients. The new 24-count packaging features individual tablet printing on the backing foil with individually perforated tablet blisters, and has an extended shelf-life of up to three years.

A person with LTBI is infected with the bacteria that cause TB, but does not feel sick, have symptoms, and cannot spread the bacteria to others. The World Health Organization estimates up to 13 million people in the U.S. have LTBI, and about five to 10 percent of them will develop TB disease if not treated. Alarming, if not treated, one person with active TB can infect on average 10 to 15 people.

Sanofi also announced today the introduction of 32-count blister package of Priftin which is tailored for use in the treatment of active TB. The new packaging features individual tablet printing on the backing foil with individually perforated tablet blisters, and an extended shelf life of up to three years.

“For more than fifty years, Sanofi has provided treatment and programs that equip patients and their healthcare providers to fight TB,” stated Paul Chew, M.D., Sanofi Global Chief Medical Officer. “We are proud to introduce packaging and extended shelf-life that reinforces our sustained commitment to the TB community.”

Priftin is an antimycobacterial that was first approved in the United States in 1998, in combination with one or more antituberculosis drugs for the treatment of active pulmonary TB caused by *Mycobacterium tuberculosis*. In December 2014, Sanofi announced the FDA approval of Priftin in combination with isoniazide (INH) for the treatment of LTBI caused by *Mycobacterium tuberculosis* in patients at high risk of progression to tuberculosis disease.

Sanofi’s ongoing collaboration with nonprofits like the Centers for Disease Control and Prevention and National Tuberculosis Controllers Association highlight the importance of public-private partnerships to address public health challenges and develop much needed treatments. Sanofi has a long-standing history in the fight against TB and believes that the availability of new Priftin packaging reinforces its commitment to patients.

Indications for Priftin (rifapentine)

Active Pulmonary Tuberculosis

Priftin (rifapentine) is indicated in adults and children 12 years and older for the treatment of active pulmonary tuberculosis caused by *Mycobacterium tuberculosis*. Priftin must always be used in combination with one or more antituberculosis drugs to which the isolate is susceptible.

Limitations of Use

Do not use Priftin monotherapy in either the initial or the continuation phases of active antituberculosis treatment. Priftin should not be used once-weekly in the continuation phase regimen in combination with isoniazid (INH) in HIV-infected patients with active pulmonary tuberculosis because of a higher rate of failure and/or relapse with rifampin-resistant organisms. Priftin has not been studied as part of the initial phase treatment regimen in HIV-infected patients



with active pulmonary tuberculosis.

Latent Tuberculosis Infection

Priftin is indicated in adults and children 2 years and older for the treatment of latent tuberculosis infection caused by *Mycobacterium tuberculosis* in patients at high risk of progression to tuberculosis disease (including those in close contact with active tuberculosis patients, recent conversion to a positive tuberculin skin test, HIV-infected patients, or those with pulmonary fibrosis on radiograph).

Limitations of Use

Active tuberculosis disease should be ruled out before initiating treatment for latent tuberculosis infection. Priftin must always be used in combination with INH as a 12-week once-weekly regimen for the treatment of latent tuberculosis infection.

- Priftin in combination with INH is not recommended for individuals presumed to be exposed to rifamycin or INH resistant *M. tuberculosis*.

Important Safety Information for Priftin (rifapentine)

Priftin is contraindicated in patients with a history of hypersensitivity to rifamycins.

Elevations of liver transaminases may occur in patients receiving Priftin. Patients should be monitored for symptoms of liver injury. Patients with abnormal liver function tests and/or liver disease or patients initiating treatment for active pulmonary tuberculosis should only be given Priftin in cases of necessity and under strict medical supervision. Discontinue Priftin if evidence of liver injury occurs.

Hypersensitivity reactions may occur in patients receiving Priftin. Signs and symptoms of these reactions may include hypotension, urticaria, angioedema, acute bronchospasm, conjunctivitis, thrombocytopenia, neutropenia or flu-like syndrome. There have been reports of anaphylaxis. Monitor patients for signs and/or symptoms of hypersensitivity reactions. If these symptoms occur, administer supportive measures and discontinue Priftin.

Higher relapse rates may occur in patients with cavitary pulmonary lesions and/or positive sputum cultures after the initial phase of active tuberculosis treatment and in patients with evidence of bilateral pulmonary disease. Monitor for signs and symptoms of relapse in these patients.

Rifapentine is an inducer of Cytochrome P450 enzymes. Concomitant use of rifapentine with other drugs metabolized by these enzymes, such as protease inhibitors, certain reverse transcriptase inhibitors, and hormonal contraception may cause a significant decrease in plasma concentrations and loss of therapeutic effect of these drugs. Dosage adjustment of the drugs may be necessary.

Priftin may produce a red-orange discoloration of body tissues and/or fluids and may permanently stain contact lenses or dentures red-orange.

Clostridium difficile-associated diarrhea (CDAD) has been reported with the use of nearly all systemic antibacterial agents, including Priftin, with severity ranging from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibacterial use. If CDAD is suspected or confirmed, discontinue antibacterial use not directed against *C. difficile* if possible and institute appropriate treatment measures.

Avoid the use of Priftin in patients with porphyria.

In Priftin studies, the most common adverse reactions with the regimen for active pulmonary tuberculosis ($\geq 1\%$) are anemia, lymphopenia, neutropenia, increased alanine aminotransferase (ALT), arthralgia, conjunctivitis, headache, vomiting, nausea, diarrhea, rash, pruritus, anorexia and lymphadenopathy. The most common adverse reaction ($\geq 1\%$) with the regimen for latent



tuberculosis infection is hypersensitivity reaction.

Please see [Full Prescribing Information](#) for Priftin (rifapentine).

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: [SAN](#)) and in New York (NYSE: [SNY](#)).

Sanofi is the holding company of a consolidated group of subsidiaries and operates in the United States as Sanofi US. For more information on Sanofi US, please visit <http://www.sanofi.us> and <http://www.news.sanofi.us/social-media> or call 1-800-981-2491.

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2014. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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