

Radiólogos se informan sobre marcapasos compatibles con resonancia magnética.

En una concurrida actividad, la Sociedad Radiológica de Puerto Rico participó del simposio educativo *MRI Safe Cardiac Implantable Devices: Patient Safety: New Pacemaker Systems*. La actividad lograda gracias a un patrocinio educativo de Medtronic sirvió para conocer la tecnología de marcapasos compatibles con resonancia magnética, qué pacientes la utilizan y las guías de seguridad necesarias al recibir pacientes con este tipo de marcapasos. El programa académico contó con la participación del electrofisiólogo Daniel Arzola y el neurorradiólogo Pedro Díaz, y el radiólogo Dennis Pérez, Presidente de la Sociedad Radiológica, hizo de moderador.

Bristol-Myers-Squibb corriendo por una cura

Por tercer año consecutivo, la farmacéutica Bristol-Myers Squibb se une al evento *Race for the Cure* de la Fundación Susan G. Komen en apoyo a las sobrevivientes y pacientes de cáncer del seno.

Además de diversas actividades de apoyo al evento, la farmacéutica otorgó un donativo por la cantidad de 15 mil dólares para apoyar los programas educativos de la Fundación Susan G. Komen.



Blanqui de Jesús, Carmen Rivera y la Directora de Susan G. Komen, Carla Sánchez, reciben el donativo de parte de Gerwin Winter, Gerente General de Bristol-Myers Squibb. Le acompañan en la entrega del donativo, el grupo de la División de Oncología de BMS, Robert Bayona, Director de la Unidad de Negocio y Carla Torres, Gerente de marca de BMS.

FDA aprueba sitagliptina y simvastatina (Juvisync™) para tratar diabetes tipo 2.

La FDA aprobó sitagliptina y simvastatina (Juvisync™), un nuevo tratamiento para la diabetes tipo 2 que combina el medicamento reductor de glucosa sitagliptina, el componente activo de sitagliptina (Januvia®) con el medicamento reductor de colesterol simvastatina (Zocor®). Es una nueva opción de tratamiento que puede ayudar a atender la población de pacientes afectados concomitantemente por la diabetes tipo 2 y la enfermedad cardiovascular, dos importantes condiciones de salud con alta prevalencia en Puerto Rico. Múltiples guías nacionales recomiendan que los pacientes con diabetes tipo 2 reciban tratamiento para el colesterol. La sitagliptina está indicada junto a la dieta y el ejercicio para mejorar el control glucémico en adultos con diabetes mellitus tipo 2. La terapia de medicamentos está indicada junto a la dieta cuando la respuesta a una dieta restringida en grasas saturadas y colesterol y otras medidas no farmacológicas solas no han sido adecuadas.

FDA aprueba uso de exenatide (Byetta®) con insulina glargina.

En un estudio, los pacientes que recibieron exenatide (Byetta®) con insulina glargina alcanzaron mejor control de la glucemia sin aumento de peso o sin aumento del riesgo de hipoglicemia, en comparación con pacientes que solo recibieron insulina glargina. La FDA aprobó esto como terapia complementaria, sin o con metformina y/o tiazolidinediona, sobre todo como alternativa para pacientes que no están alcanzando las metas de tratamiento deseadas, manifestó John Buse, MD, Director del Centro de Diabetes de *University of North Carolina*, Chapel Hill.

Estas notas de prensa o informativas pueden contener ciertas declaraciones prospectivas sobre el potencial de algunos fármacos. Sin embargo, al igual que con cualquier compuesto farmacéutico aprobados, o más aún en proceso de desarrollo, existen riesgos e incertidumbres significativos en el proceso de desarrollo y de revisión regulatorias. No hay garantías de que el producto reciba las aprobaciones regulatorias, que la aprobación regulatoria sea para la(s) indicación(es) prevista(s) por las compañías o que los estudios posteriores y la experiencia de los pacientes sean compatibles con los hallazgos del estudio hasta la fecha, ni en el caso de medicamentos aprobados que estos continúen siendo un éxito terapéutico o comercial. No asumimos responsabilidad de actualizar declaraciones o información presentada.



Stelara[®]

(ustekinumab)

STELARA[®] is indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

STELARA[®], available as 45 mg and 90 mg, is a subcutaneous injection that should only be administered by a healthcare provider to patients who have regular follow-up with a physician.¹

Selected Safety Information

STELARA[®] is an immunosuppressant and may increase the risk of infections, reactivation of latent infections, and malignancies. Serious adverse reactions have been reported in STELARA[®]-treated patients, including bacterial, fungal, and viral infections, malignancies, serious allergic reactions and one case of Reversible Posterior Leukoencephalopathy Syndrome (RPLS).

STELARA[®] should not be given to patients with any clinically important active infection. Patients should be evaluated for tuberculosis prior to initiating treatment with STELARA[®]. Live vaccines should not be given to patients receiving STELARA[®]. If RPLS is suspected, discontinue STELARA[®].

Please see related and other Important Safety Information for STELARA[®] within this advertisement.

$$\begin{array}{r} 365 \\ -4 \\ \hline 361 \end{array}$$

Days

Maintenance doses a year,
after 2 starter doses

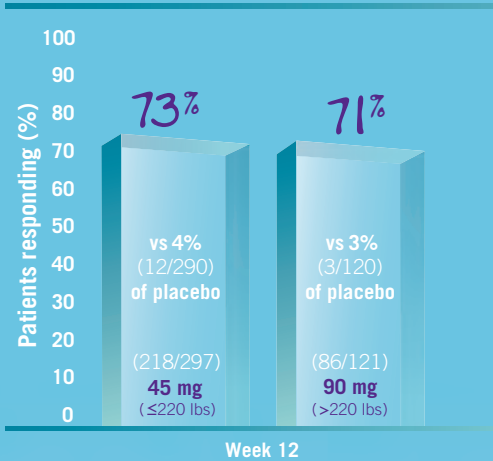
Days free of dosing



STELARA®: SIGNIFICANT CLEARANCE WITH JUST 4 DOSES A YEAR, AFTER 2 STARTER DOSES¹

STELARA® is a subcutaneous injection dosed once every 12 weeks after 2 starter doses at Weeks 0 and 4¹

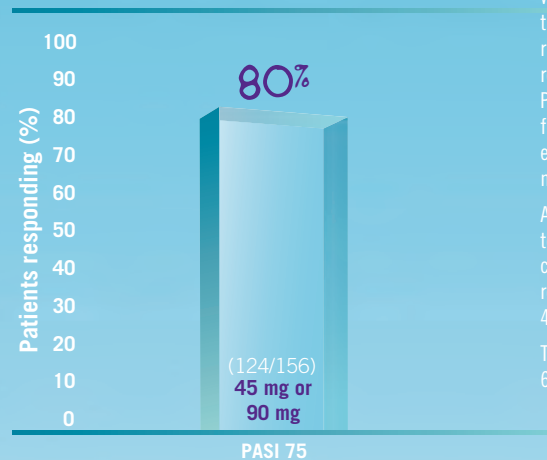
PASI 75 response at Week 12¹



- The primary endpoint was PASI 75 at Week 12 (45 mg: 67% [n=409]; 90 mg: 76% [n=411]; placebo: 4% [n=410]; $P < 0.0001$ vs placebo for each dose).^{1,2}
- **Treatment success** (defined as PGA score of Cleared or Minimal) **was achieved at Week 12 in 7 out of 10 patients** in the 45 mg and 90 mg groups [68% (277/409) and 73% (300/411), respectively] compared with 4% (18/410) of placebo patients ($P < 0.0001$).^{1,2}

PHOENIX 2 evaluated 1230 patients who began the study receiving STELARA® 45 mg or 90 mg or placebo. Patients randomized to STELARA® received STELARA® at Weeks 0 and 4, followed by the same dose every 12 weeks through Week 28. Patients in the placebo group (n=410) crossed over to receive either STELARA® 45 mg or 90 mg at Weeks 12 and 16, followed by the same dose every 12 weeks. Eligible patients were adults with a diagnosis of plaque psoriasis for ≥6 months involving ≥10% Body Surface Area (BSA), PASI score ≥12, and who were candidates for phototherapy or systemic therapy.^{1,2}

PASI 75 response at Week 100 in patients who were rerandomized to continue treatment after responding to STELARA® at Weeks 28 and 40³



PHOENIX 1 evaluated 766 patients who received STELARA® or placebo. The study design was identical to PHOENIX 2 through Week 28. Inclusion criteria were consistent with PHOENIX 2. At Week 40, patients initially randomized to STELARA® who were PASI 75 responders at both Weeks 28 and 40 were rerandomized either to continue every-12-week dosing with STELARA® or to placebo. Patients randomized to placebo at Week 40 were retreated with their original dosing regimen when they lost ≥50% of the PASI improvement achieved at Week 40. Patients rerandomized to STELARA® at Week 40 were considered treatment failures if they discontinued STELARA® due to unsatisfactory therapeutic effect, experienced an adverse event of worsening of psoriasis, or started non-topical protocol-prohibited medications.^{1,3,4}

After Week 76, treatment was unblinded, and treatment failure rules were relaxed to allow for use of concomitant topical medications, except for high-potency corticosteroids (10 patients randomized to STELARA® every 12 weeks at Week 40 received concomitant topicals between Week 76 and 100; PASI 75 was achieved in 4 out of 10 of these patients at Week 100).³

The primary endpoint was PASI 75 at Week 12 (45 mg: 67% [n=255]; 90 mg: 66% [n=256]; placebo: 3% [n=255]; $P < 0.0001$ vs placebo for each dose).^{1,4}

Results from an open-label extension at Week 100; concomitant topicals were allowed after Week 76.³

The safety and efficacy of STELARA® have not been evaluated beyond two years.¹

Selected Safety Information

STELARA® is an immunosuppressant and may increase the risk of infections, reactivation of latent infections, and malignancies. Serious adverse reactions have been reported in STELARA®-treated patients, including bacterial, fungal, and viral infections, malignancies, serious allergic reactions and one case of Reversible Posterior Leukoencephalopathy Syndrome (RPLS).

STELARA® should not be given to patients with any clinically important active infection. Patients should be evaluated for tuberculosis prior to initiating treatment with STELARA®. Live vaccines should not be given to patients receiving STELARA®. If RPLS is suspected, discontinue STELARA®.

Please see related and other Important Safety Information for STELARA® on reverse page.



IMPORTANT SAFETY INFORMATION

Infections

STELARA® (ustekinumab) may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections were reported. Infections requiring hospitalization included cellulitis, diverticulitis, osteomyelitis, gastroenteritis, pneumonia, and urinary tract infections. STELARA® should not be given to patients with a clinically important active infection and should not be administered until the infection resolves or is adequately treated. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. Exercise caution when considering use of STELARA® in patients with a chronic infection or a history of recurrent infection.

Theoretical Risk for Vulnerability to Particular Infections

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacterium, *Salmonella*, and *Bacillus Calmette-Guerin* (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients. It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with STELARA® will be susceptible to these types of infections. Consider appropriate diagnostic testing as dictated by clinical circumstances.

Pre-Treatment Evaluation of Tuberculosis (TB)

Evaluate patients for TB prior to initiating treatment with STELARA®. STELARA® should not be given to patients with active TB. Initiate treatment of latent TB before administering STELARA®. Patients should be monitored closely for signs and symptoms of active TB during and after treatment with STELARA®.

Malignancies

STELARA® is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among patients who received STELARA® in clinical studies. The safety of STELARA® has not been evaluated in patients who have a history of malignancy or who have a known malignancy.

Hypersensitivity Reactions

Serious allergic reactions, including angioedema and possible anaphylaxis, have been reported. Discontinue STELARA® and institute appropriate therapy if an anaphylactic or other serious allergic reaction occurs.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

One case of RPLS has been reported in a STELARA®-treated patient. If RPLS is suspected, discontinue STELARA® and administer appropriate treatment.

RPLS is a neurological disorder, which is not caused by an infection or demyelination. RPLS can present with headache, seizures, confusion, and visual disturbances. RPLS has been associated with fatal outcomes.

Immunizations

Prior to initiating therapy with STELARA®, patients should receive all immunizations recommended by current guidelines. Patients being treated with STELARA® should not receive live vaccines. BCG vaccines should not be given during treatment or within one year of initiating or discontinuing STELARA®. Exercise caution when administering live vaccines to household contacts of STELARA® patients, as shedding and subsequent transmission to STELARA® patients may occur. Non-live vaccinations received during a course of STELARA® may not elicit an immune response sufficient to prevent disease.

Concomitant Therapies

The safety of STELARA® in combination with other immunosuppressive agents or phototherapy has not been evaluated. Ultraviolet-induced skin cancers developed earlier and more frequently in mice genetically manipulated to be deficient in both IL-12 and IL-23 or IL-12 alone. The relevance of these findings in mouse models for malignancy risk in humans is unknown.

Theoretical Risk of Immunotherapy

STELARA® may decrease the protective effect of allergy immunotherapy and may increase the risk of allergic reaction to allergen immunotherapy. Exercise caution in patients receiving or who have received allergy immunotherapy, particularly for anaphylaxis.

Most Common Adverse Reactions

The most common adverse reactions ($\geq 3\%$ and higher than that with placebo) in clinical trials for STELARA® 45 mg, STELARA® 90 mg, or placebo were: nasopharyngitis (8%, 7%, 8%), upper respiratory tract infection (5%, 4%, 5%), headache (5%, 5%, 3%), and fatigue (3%, 3%, 2%), respectively.

Please see Brief Summary of Prescribing Information for STELARA® within this advertisement.

References: 1. STELARA® Prescribing Information. Horsham, PA: Janssen Biotech, Inc. 2. Papp KA, Langley RG, Lebwohl M, et al; for the PHOENIX 2 study investigators. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 52-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 2). *Lancet*. 2008;371(9625):1675-1684. 3. Data on file. Janssen Biotech, Inc. 4. Leonardi CL, Kimball AB, Papp KA, et al; for the PHOENIX 1 study investigators. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 76-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 1). *Lancet*. 2008;371(9625):1665-1674.

Brief Summary of Prescribing Information for STELARA® (ustekinumab)

STELARA® Injection, for subcutaneous use

See package insert for Full Prescribing Information

INDICATIONS AND USAGE: STELARA® is indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. **CONTRAINDICATIONS:** None. **WARNINGS AND PRECAUTIONS: Infections** STELARA® may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections were observed in subjects receiving STELARA® (see *Adverse Reactions*). STELARA® should not be given to patients with any clinically important active infection. STELARA® should not be administered until the infection resolves or is adequately treated. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. Exercise caution when considering the use of STELARA® in patients with a chronic infection or a history of recurrent infection. Serious infections requiring hospitalization occurred in the psoriasis development program. These serious infections included cellulitis, diverticulitis, osteomyelitis, viral infections, gastroenteritis, pneumonia, and urinary tract infections. **Theoretical Risk for Vulnerability to Particular Infections** Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria (including nontuberculous, environmental mycobacteria), salmonella (including nontyphi strains), and Bacillus Calmette-Guerin (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients. It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with STELARA® will be susceptible to these types of infections. Appropriate diagnostic testing should be considered, e.g., tissue culture, stool culture, as dictated by clinical circumstances. **Pre-treatment Evaluation for Tuberculosis** Evaluate patients for tuberculosis infection prior to initiating treatment with STELARA®. Do not administer STELARA® to patients with active tuberculosis. Initiate treatment of latent tuberculosis prior to administering STELARA®. Consider anti-tuberculosis therapy prior to initiation of STELARA® in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving STELARA® should be monitored closely for signs and symptoms of active tuberculosis during and after treatment. **Malignancies** STELARA® is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among subjects who received STELARA® in clinical studies (see *Adverse Reactions*). In rodent models, inhibition of IL-12/IL-23p40 increased the risk of malignancy (see *Nonclinical Toxicology*). The safety of STELARA® has not been evaluated in patients who have a history of malignancy or who have a known malignancy. **Hypersensitivity Reactions** Serious allergic reactions, including angioedema and possible anaphylaxis, have been reported post-marketing. If an anaphylactic or other serious allergic reaction occurs, discontinue STELARA® and institute appropriate therapy [see *Adverse Reactions*]. **Reversible Posterior Leukoencephalopathy Syndrome** One case of reversible posterior leukoencephalopathy syndrome (RPLS) was observed during the clinical development program which included 3523 STELARA®-treated subjects. The subject, who had received 12 doses of STELARA® over approximately two years, presented with headache, seizures and confusion. No additional STELARA® injections were administered and the subject fully recovered with appropriate treatment. RPLS is a neurological disorder, which is not caused by demyelination or a known infectious agent. RPLS can present with headache, seizures, confusion and visual disturbances. Conditions with which it has been associated include preeclampsia, eclampsia, acute hypertension, cytotoxic agents and immunosuppressive therapy. Fatal outcomes have been reported. If RPLS is suspected, STELARA® should be discontinued and appropriate treatment administered. **Immunizations** Prior to initiating therapy with STELARA®, patients should receive all immunizations appropriate for age as recommended by current immunization guidelines. Patients being treated with STELARA® should not receive live vaccines. BCG vaccines should not be given during treatment with STELARA® or for one year prior to initiating treatment or one year following discontinuation of treatment. Caution is advised when administering live vaccines to household contacts of patients receiving STELARA® because of the potential risk for shedding from the household contact and transmission to patient. Non-live vaccinations received during a course of STELARA® may not elicit an immune response sufficient to prevent disease. **Concomitant Therapies** The safety of STELARA® in combination with other immunosuppressive agents or phototherapy has not been evaluated. Ultraviolet-induced skin cancers developed earlier and more frequently in mice genetically manipulated to be deficient in both IL-12 and IL-23 or IL-12 alone (see *Nonclinical Toxicology*). **Theoretical Risk of Immunotherapy** STELARA® has not been evaluated in patients who have undergone allergy immunotherapy. STELARA® may decrease the protective effect of allergy immunotherapy and may increase the risk of an allergic reaction to a dose of allergen immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergy immunotherapy, particularly for anaphylaxis. **ADVERSE REACTIONS:** The following serious adverse reactions are discussed elsewhere in the label: Infections (see *Warnings and Precautions*); Malignancies (see *Warnings and Precautions*); and RPLS (see *Warnings and Precautions*). **Clinical Studies Experience** The safety data reflect exposure to STELARA® in 2266 psoriasis subjects, including 1970 exposed for at least 6 months, 1285 exposed for at least one year, and 373 exposed for at least 18 months. Because clinical trials are conducted under widely

STELARA® (ustekinumab)

varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Adverse reactions listed below are those that occurred at a rate of at least 1% and at a higher rate in the STELARA® groups than the placebo group during the placebo-controlled period of STUDY 1 and STUDY 2. The numbers (percentages) of adverse reactions reported for placebo-treated patients (n=665), patients treated with 45 mg STELARA® (n=664), and patients treated with 90 mg STELARA® (n=666), respectively, were: *Nasopharyngitis*: 51 (8%), 56 (8%), 49 (7%); *Upper respiratory tract infection*: 30 (5%), 36 (5%), 28 (4%); *Headache*: 23 (3%), 33 (5%), 32 (5%); *Fatigue*: 14 (2%), 18 (3%), 17 (3%); *Diarrhea*: 12 (2%), 13 (2%), 13 (2%); *Back pain*: 8 (1%), 9 (1%), 14 (2%); *Dizziness*: 8 (1%), 8 (1%), 14 (2%); *Pharyngolaryngeal pain*: 7 (1%), 9 (1%), 12 (2%); *Pruritus*: 9 (1%), 10 (2%), 9 (1%); *Injection site erythema*: 3 (<1%), 6 (1%), 13 (2%); *Myalgia*: 4 (1%), 7 (1%), 8 (1%); *Depression*: 3 (<1%), 8 (1%), 4 (1%). Adverse drug reactions that occurred at rates less than 1% included: cellulitis and certain injection site reactions (pain, swelling, pruritus, induration, hemorrhage, bruising, and irritation). One case of RPLS occurred during clinical trials (see *Warnings and Precautions*). **Infections** In the placebo-controlled period of clinical studies of psoriasis subjects (average follow-up of 12.6 weeks for placebo-treated subjects and 13.4 weeks for STELARA®-treated subjects), 27% of STELARA®-treated subjects reported infections (1.39 per subject-year of follow-up) compared with 24% of placebo-treated subjects (1.21 per subject-year of follow-up). Serious infections occurred in 0.3% of STELARA®-treated subjects (0.01 per subject-year of follow-up) and in 0.4% of placebo-treated subjects (0.02 per subject-year of follow-up) (see *Warnings and Precautions*). In the controlled and non-controlled portions of psoriasis clinical trials, 61% of STELARA®-treated subjects reported infections (1.24 per subject-year of follow-up). Serious infections were reported in 0.9% of subjects (0.01 per subject-year of follow-up). **Malignancies** In the controlled and non-controlled portions of psoriasis clinical trials, 0.4% of STELARA®-treated subjects reported malignancies excluding non-melanoma skin cancers (0.36 per 100 subject-years of follow-up). Non-melanoma skin cancer was reported in 0.8% of STELARA®-treated subjects (0.80 per 100 subject-years of follow-up) (see *Warnings and Precautions*). Serious malignancies included breast, colon, head and neck, kidney, prostate, and thyroid cancers. **Immunogenicity** The presence of ustekinumab in the serum can interfere with the detection of anti-ustekinumab antibodies resulting in inconclusive results due to assay interference. In STUDIES 1 and 2, antibody testing was done at time points when ustekinumab may have been present in the serum. In STUDY 1 the last ustekinumab injection was between Weeks 28 and 48 and the last test for anti-ustekinumab antibodies was at Week 52. In STUDY 2 the last ustekinumab injection was at Week 16 and the last test for anti-ustekinumab antibodies was at Week 24. In STUDY 1 (N=743), antibody results were found to be positive, negative, and inconclusive in 38 (5%), 351 (47%), and 354 (48%) patients, respectively. In STUDY 2 (N=1198), antibody results were found to be positive, negative, and inconclusive in 33 (3%), 90 (8%), and 1075 (90%) patients, respectively. The data reflect the percentage of subjects whose test results were positive for antibodies to ustekinumab in a bridging immunoassay, and are highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors, including sample handling, timing of sample collection, concomitant medications and underlying disease. For these reasons, comparison of the incidence of antibodies to ustekinumab with the incidence of antibodies to other products may be misleading. **Post-marketing Experience** Adverse reactions have been reported during post-population use with STELARA®. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to STELARA® exposure. **Immune system disorders:** Serious allergic reactions (including angioedema, dyspnea and hypotension), hypersensitivity reactions (including rash and urticaria). **DRUG INTERACTIONS:** Drug interaction studies have not been conducted with STELARA®. **Live Vaccines** Live vaccines should not be given concurrently with STELARA® (see *Warnings and Precautions*). **Concomitant Therapies** The safety of STELARA® in combination with immunosuppressive agents or phototherapy has not been evaluated (see *Warnings and Precautions*). **CYP450 Substrates** The formation of CYP450 enzymes can be altered by increased levels of certain cytokines (e.g., IL-1, IL-6, IL-10, TNF α , IFN) during chronic inflammation. Thus, ustekinumab could normalize the formation of CYP450 enzymes. A role for IL-12 or IL-23 in the regulation of CYP450 enzymes has not been reported. However, upon initiation of ustekinumab in patients who are receiving concomitant CYP450 substrates, particularly those with a narrow therapeutic index, monitoring for therapeutic effect (e.g., for warfarin) or drug concentration (e.g., for cyclosporine) should be considered and the individual dose of the drug adjusted as needed (see *Clinical Pharmacology*). **USE IN SPECIFIC POPULATIONS: Pregnancy** *Pregnancy Category B* There are no studies of STELARA® in pregnant women. STELARA® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. No teratogenic effects were observed in the developmental and reproductive toxicology studies performed in cynomolgus monkeys at doses up to 45 mg/kg ustekinumab, which is 45 times (based on mg/kg) the highest intended clinical dose in psoriasis patients (approximately 1 mg/kg based on administration of a 90 mg dose to a 90 kg psoriasis patient). Ustekinumab was

STELARA® (ustekinumab)

tested in two embryo-fetal development toxicity studies. Pregnant cynomolgus monkeys were administered ustekinumab at doses up to 45 mg/kg during the period of organogenesis either twice weekly via subcutaneous injections or weekly by intravenous injections. No significant adverse developmental effects were noted in either study. In an embryo-fetal development and pre- and post-natal development toxicity study, three groups of 20 pregnant cynomolgus monkeys were administered subcutaneous doses of 0, 22.5, or 45 mg/kg ustekinumab twice weekly from the beginning of organogenesis in cynomolgus monkeys to Day 33 after delivery. There were no treatment-related effects on mortality, clinical signs, body weight, food consumption, hematology, or serum biochemistry in dams. Fetal losses occurred in six control monkeys, six 22.5 mg/kg-treated monkeys, and five 45 mg/kg-treated monkeys. Neonatal deaths occurred in one 22.5 mg/kg-treated monkey and in one 45 mg/kg-treated monkey. No ustekinumab-related abnormalities were observed in the neonates from birth through six months of age in clinical signs, body weight, hematology, or serum biochemistry. There were no treatment-related effects on functional development until weaning, functional development after weaning, morphological development, immunological development, and gross and histopathological examinations of offsprings by the age of 6 months. **Nursing Mothers** Caution should be exercised when STELARA® is administered to a nursing woman. The unknown risks to the infant from gastrointestinal or systemic exposure to ustekinumab should be weighed against the known benefits of breast-feeding. Ustekinumab is excreted in the milk of lactating monkeys administered ustekinumab. IgG is excreted in human milk, so it is expected that STELARA® will be present in human milk. It is not known if ustekinumab is absorbed systemically after ingestion; however, published data suggest that antibodies in breast milk do not enter the neonatal and infant circulation in substantial amounts. **Pediatric Use** Safety and effectiveness of STELARA® in pediatric patients have not been evaluated. **Geriatric Use** Of the 2266 psoriasis subjects exposed to STELARA®, a total of 131 were 65 years or older, and 14 subjects were 75 years or older. Although no differences in safety or efficacy were observed between older and younger subjects, the number of subjects aged 65 and over is not sufficient to determine whether they respond differently from younger subjects. **OVERDOSAGE:** Single doses up to 4.5 mg/kg intravenously have been administered in clinical studies without dose-limiting toxicity. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment be instituted immediately. **PATIENT COUNSELING INFORMATION:** Instruct patients to read the Medication Guide before starting STELARA® therapy and to reread the Medication Guide each time the prescription is renewed. **Infections** Inform patients that STELARA® may lower the ability of their immune system to fight infections. Instruct patients of the importance of communicating any history of infections to the doctor, and contacting their doctor if they develop any symptoms of infection. **Malignancies** Patients should be counseled about the risk of malignancies while receiving STELARA®. **Allergic Reactions** Advise patients to seek immediate medical attention if they experience any symptoms of serious allergic reactions.

Prefilled Syringe Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, License No. 1864 at Baxter Pharmaceutical Solutions, Bloomington, IN 47403

Vial Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, License No. 1864 at Cilag AG, Schaffhausen, Switzerland

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25ST11142



Importante apoyo de NHI a Recinto de Ciencias Médicas

El Programa “Centros de Investigación en Instituciones Minoritarias” del Recinto de Ciencias Médicas (RCM) recibió un donativo de \$13.6 millones de los Institutos Nacionales de la Salud para establecer un centro de investigación que facilite la investigación competitiva en el RCM durante los próximos cinco años. El anuncio fue hecho por la Dra. Emma Fernández-Repollet, Profesora de Farmacología e Investigadora Principal de RCM que señaló: “El apoyo a la infraestructura que sostiene la investigación es indispensable para atender y entender las desigualdades en la salud, así como para mejorar la salud y la calidad de vida de nuestra población”. El Programa desarrollará una infraestructura de avanzada, que incluye instalaciones en las áreas de proteómica clínica, genética molecular, farmacogenómica, neurogenética, informática y telecomunicaciones. Estas localidades ofrecerán servicios de apoyo para conducir estudios colaborativos sobre condiciones tales como cáncer, desórdenes neurológicos, VIH, enfermedades infecciosas y diabetes.

Expertos internacionales evalúan iniciativas para vacuna contra el dengue.

Dengue v2V, un grupo de expertos internacionales en dengue, salud pública y vacunación, sostuvo su reunión anual en Puerto Rico en noviembre de 2011, para seguir delineando los pasos para la introducción de una vacuna del dengue una vez se obtenga la licencia. Asistieron expertos de Puerto Rico, Asia, Australia, América del Sur, Estados Unidos y Europa.

“Puerto Rico es un lugar relevante para esta reunión por su localización y experiencia, tanto con actividad de dengue endémica como epidémica,” dijo el Dr. Harold Margolis, Director de la Sección de Dengue del Centro de Control de Enfermedades (CDC), co-presidente de la reunión. “Además de las medidas para controlar el mosquito, una vacuna contra el dengue es la mejor forma de control”.

El dengue es una amenaza para la mitad de la población mundial y una prioridad de salud pública en América Latina y Asia. Estudios recientes estiman que se infectan 50 a 100 millones de personas anualmente, de las cuales 500 000 desarrollan dengue de fiebre hemorrágico, falleciendo por dengue 22 000 personas al año.



Dr. Harold Margolis, Dr. Jorge Pérez Galván y Prof. Torresi.

Premio Honor 2011 conferido a Hematólogo-Oncólogo

El Dr. Nelson Robles Cardona es reconocido por su labor en beneficio de los pacientes de cáncer, en especial en Aibonito y el centro de la isla. Por ello la Cooperativa San José confirió el premio Honor 2011. El Dr. Nelson Robles expresó: “Yo trabajo día a día a favor de los pacientes de cáncer a través de los programas que hemos creado y no pienso que esto amerite un premio. Lo acepto ya que entiendo que necesitamos que se conozca la labor del Centro de Cáncer de la Montaña y del acceso que tiene la población a los servicios de calidad que hemos creado...”. Cabe destacar que la Fundación Menonita de Cáncer es una iniciativa creada por el Dr. Robles en conjunto con el Hospital Menonita.



El Dr. Nelson Robles recibe de manos del Sr. Ricky Berríos, presidente ejecutivo de la Cooperativa San José, el premio Honor 2011. Acompañan miembros de la junta de directores y la Sra. Carmen Cardona, madre del homenajeado.

Distinciones en Manatí Medical Center



Dr. Luis Rosa Toledo, Dr. Carlos Discier, Dra. Mayra Rivera, Dr. José Martínez Barroso, Sr. José L. Quirós y Lcdo. Jorge Galva.

Manatí Medical Center (MMC) celebró su 13ª Convención Médica el pasado fin de semana en el Hotel Caribe Hilton, en la que estuvieron presentes varios de los 250 médicos que componen su facultad médica. Se distinguió al Dr. Jorge Jiménez, médico de familia, y a la Dra. Mayra Rivera, hematóloga-oncóloga.

Con optimismo, se recibe designación de Procurador de Salud, Dr. Carlos Mellado.

El Colegio de Médicos Cirujanos de Puerto Rico respaldó la designación del Dr. Carlos Mellado como Procurador de la Salud. “Nuestro endoso no se da en el vacío, pues conocemos de las excelentes cualidades de este profesional. Así, nos hemos reunido para discutir la reglamentación pertinente al manejo de pacientes en los consultorios médicos, para coordinar la participación en adiestramientos de médicos y en otros asuntos. La actitud del Dr. Mellado ha sido de disponibilidad absoluta para reunirse y discutir con cordura y mesura *issues* sensitivos”, indicó la Dra. Alicia Feliberti Irizarry, Presidenta del gremio.

“Las decisiones y posiciones que he asumido dentro de mis funciones como Procurador son el resultado de un análisis serio, independiente y cuidadoso del asunto o controversia planteada, y de la evaluación de la realidad social en la que nuestra decisión será aplicada. Pues tras cada expediente ante mi consideración existen un rostro, un paciente y un proveedor, que debe tenerse en cuenta a la hora de impartir justicia”, indicó el nuevo procurador. La Procuraduría de Salud actualmente elabora un nuevo manual de procedimientos con el propósito de crear un nuevo sistema de atención de casos y querellas y ha restablecido el proceso de vistas administrativas con el fin de atender de forma ágil los asuntos y querellas que impliquen imposición de multa administrativa a tenor con el debido proceso de ley.