## Lymphogranuloma Venereum Cases Increasing

BY BRUCE JANCIN

MAUI, HAWAII — Lymphogranuloma venereum is making a comeback, and this time around the STD looks nothing like it did during residency training.

The new clinical picture of lymphogranuloma venereum (LGV) is proctitis in slightly older gay men, Dr. Theodore Rosen explained at the annual Hawaii dermatology seminar sponsored by Skin Disease Education Foundation.

In developed countries, "the resurgence is virtually all in men who have sex with men, more than 35 years old, white, sometimes coinfected with HIV or hepatitis C. It presents as proctitis, which could be anything from a mild anorectal discharge, pain, bloody stools, to a feeling of incomplete evacuation. And we've now seen two cases that presented with severe rectal itching and that's all," said Dr. Rosen, professor of dermatology at Baylor College of Medicine, Houston.

The classic form involves infection of the inguinal lymphatics and lymph nodes, resulting in buboes that can make walking difficult. This form has always been rare in industrialized countries; even in underdeveloped tropical countries where it's endemic it accounts for less than 10% of cases of genital ulcer disease, he noted.

Dr. Rosen urged physicians to consid-

er LGV as a possibility in patients who present with proctitis and fall within the appropriate demographic group. The diagnosis is established by obtaining a rectal swab and sending it to the Centers for Disease Control and Prevention. The treatment for LGV is doxycycline at 100 mg b.i.d. for 21 days. Minocycline is an effective alternative, he added.

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WARNING: Suicidality and Antidepressant Drugs
Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Pristiq or any other antidepressant is a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Pristig is not approved for use in pediatric patients [see Warnings and Precautions (5.1), Use in Specific Populations (8.4), and Patient Counseling Information (17.1 in the full prescribing information).

Is not approved for use in pediatric patients [see Warmings and Precautions (3.1), Use in Specific Populations (8.4), and Patient Counseling Information (17.1 in the full prescribing information)].

INDICATIONS AND USAGE: Pristiq, a selective serotonin and norepinephrine reuptake inhibitor (SNRI), is indicated for the treatment of major depressive disorder (MDD).

CONTRAINDICATIONS: Hypersensitivity: Hypersensitivity to desvenlafaxine succinate, venlafaxine hydrochloride or to any excipients in the Pristiq formulation. Monoamine Oxidase Inhibitors- Pristiq must not be used concomitantly in patients taking monoamine oxidase inhibitors (MAOIs) or in patients desvenlafaxine, at least 7 days should be allowed after stopping Pristiq before starting an MAOI [see Dosage and Administration (2.5) in the full prescribing information].

WARNINGS AND PRECAUTIONS: Clinical Worsening and Suicide Risk- Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychilatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and these entry and the patients during and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychilatric disorders. Short-term studies did not show an increas drugs increase the risk of sucidal thinking and behavior (sucidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older. The pooled analyses of placebo-controlled studies in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term studies in adults with MDD or other psychiatric disorders included a total of 24 short-term studies in adults with MDD or other psychiatric disorders included a total of 295 short-term studies (median duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences to assolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in Table 1 of the full prescribing information. No suicides occurred in any of the pediatric studies. There were suicides in the adult studies, but the number was not sufficient to reach any conclusion about drug effect on suicide. It is unknown whether the suicidality risk extends to longerterm use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance studies in adults with depression that the use of antidepressants can delay the recurrence of depression. All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a c symptoms are severe, abrupt in onset, or were not part of the patients presenting symptoms. If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms [see Warnings and Precautions (5.9) and Dosage and Administration (2.3) in the full prescribing information of a describino of the risks of discontinuation of Pristig.] Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for Pristiq should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose. Screening patients for bipolar disorder- A major depressive episode may be the initial presentation of bipolar disorder it is generally believed (though not established in controlled studies) that treating such an episode with an antidepressant alone may increase the likelihood of recipitation of a mixed/manic episode with an antidepressant alone may increase the likelihood of recipitation of a mixed/manic episode in patients at risk for bipolar disorder, whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder, such as a su

of bleeding associated with the concomitant use of Pristiq and NSAIDs, aspirin, or other drugs that affect coagulation or bleeding. Narrow-angle Glaucoma- Mydiasis has been reported in association with Pristiq. Therefore, patients with raised intraocular pressure or those at risk of acute narrow-angle glaucoma (angle-closure glaucoma) should be monitored. Activation of Mania/Hypomania- During all MDD and VMS (vasomotor symptoms) phase 2 and phase 3 studies, main was reported for approximately 0.1% of patients treated with Pristiq. Activation of mania/Hypomania has also been reported in a small proportion of patents with major affective disorder who were treated with other marketed antidepressants. As with all antidepressants, Pristiq should be used cautiously in patients with a history or family history of mania or hypomania. Cardiovascular, cerebrovascular, or lipid metabolism disorders [see Adverse Reactions 6.1], Increases in blood pressure and heart rate were observed in clinical studies with Pristiq. Pristiq has not been evaluated systematically in patients with a recent history of myocardial infarction, unstable heart disease, uncorrolled hypertension, or cerebrovascular disease. Patients with these diagnoses, except for cerebrovascular disease, were excluded from clinical studies. Serum Cholesterol and Triglyceride Elevation— Dose-related elevations in fasting serum total cholesterol, LDL (low density lipoprotein) cholesterol, and triglycerides were observed in the controlled studies. Measurement of serum lipids should be considered during treatment with Pristiq (see Adverse Reactions) (6.1). Discontinuation of Treatment with Pristiq during clinical studies in Major Depressive Disorder. Abrupt discontinuation or dose reduction has been associated with the appearance of new symptoms that included dizziness, nuseea, headache, irritability, insommia, darmea, anxiety, Vafigue, abnormal dreams, and hyperhidrosis. In general, discontinuation events occurred more frequently with longer duration of therapy burni

therapy have been rarely reported. The possibility of these adverse events should be considered in patients treated with Pristiq who present with progressive dyspenae, cough, or chest disconflort. Such patients should undergo a prompt medical evaluation, and discontinuation of Pristiq should be considered.

ADVERSE REACTIONS: Clinical Studies Experience: The most commonly observed adverse reactions in Pristiq-freated MDD patients in short-term fixed-dose studies (incidence ≥5% and at least twice hard of placebo in the 50 or 100-mg dose groups) were nausea, alizanies, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anviety, and specific male sexual function disorders. Adverse reactions reported as reasons for discontinuation of treatment. The most common adverse reactions leading to discontinuation in at least 2% of the Pristiq-treated patients in the short-term studies, up to 8 weeks, were nausea (4%), diszlamess, headench and vontiling (2% eact); in the long-term study, up to 9 months, the most common was womiting (2%). Common adverse reactions that occurred in ≥2% of Pristiq-treated MDD patients at any dose in the 8-week, placebo-controlled mice studies. In general, the adverse reactions were most frequent in the first week of treatment. Cardiac, disorders. Palpitations, Tachycardia, Blood pressure increased; castrointestinal disorders: Nausea. Dry mouth, Diarrhea, Constipation, Vontiling, General disorders and administration site conditions: Patigue, Chilis, Feeling jittery, Asthenia; Metalogism and nutrition disorders: Decreased appetite, weight decreased, Neurous system disorders. Disorders in Somnia, Anxiety, Moracic, and mediastinal disorders: Naunia, Figural and surface, and subculaneous tissue disorders: Hyperhidrosis, Resh; Special Senses: Wision blurred; Mydrases, Ilinitus, Dysguesia; Vascular Disorders: Hyperhidrosis, Palpitation adverse reactions decreased, Orgasam abnormal, Ejaculation delayed, Erectell dysfunction, Ejaculation disorders, Epischion, Moragas and Procautions,

reported in patients who have recently been discontinued from a monoamine oxidase inhibitor (MAOI) and started on antidepressants with pharmacological properties similar to Pristin (SNRIs or SSRIs), or who have recently had SNRI or SSRI therapy discontinued prior to initiation of an MAOI Issee Contraindications (£2]. Serotonergio Drugs—Based on the mechanism of action of Pristin, and the potential for serotonin syndrome, caution is advised when Pristin is coadministered with other drugs that may affect the serotonergic neurotransmitter systems [see Warnings and Precautions 6:2]. Drugs that Interfere with Hemostasis (e.g., NSAIDs, Aspirin, and Warfarin)—Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies of case-control and cohort design have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal beleding. These studies have also shown that concurrent use of an NSAID or aspirin may potentiate this risk of bleeding. Altered anticoagulant effects, including increased beleding, have been reported when SSRIs and SNRIs are coadministered with warfarin. Patients receiving warfarin therapy should be carefully monitored when Pristing is initiated or discontinued. Ethanol — A clinical study has shown that desvendations does not increase the impairment of merit and minotor skills caused by ethanol. However, as with all CNS-active drugs, patients. Service of the properties of the studies of the patients of the patients. The patients of t

Hepatic Impairment—The mean t<sub>s</sub>, changed from approximately 10 hours in healthy subjects and subjects with mild hepatic impairment to 13 and 14 hours in moderate and severe hepatic impairment, respectively. No adjustment in starting dosage is necessary for patients with hepatic impairment.

OVERDOSAGE: Human Experience with Overdosage—There is limited clinical experience with desvenlafaxine succinate overdosage in humans. In premarketing clinical studies, no cases of fatal acute overdose of desvenlafaxine were reported. The adverse reactions reported within 5 days of an overdose > 600 mg that were possibly related to Pristig included headache, vomiting, agitation, dizziness, nausea, constipation, diarrhea, dry mouth, paresthesia, and tachycardia. Desvenlafaxine (Pristig) is the major active metabolite of venidafaxine. Overdose experience reported with venlafaxine (the parent drug of Pristig) has presented below; the identical information can be found in the Overdosage section of the venidarianie package insert. In postmarketing experience, overdose with venidariane (Pristig) is occurred predominantly in combination with alcohol and/or other drugs. The most commonly reported events in overdosage include tachycardia, changes in level of consciousness (ranging from somnolence to coma), mydriasis, seizures, and vomiting. Electrocardiogram changes (e.g., prolongation of QT interval, bundle branch block, QRS prolongation), sinus and ventricular tachycardia, bradycardia, hypotension, rhabdomyolysis, vertigo, liver necrosis, serotonin syndrome, and death have been reported. Published retrospective studies report that venlafaxine overdosage may be associated with an increased risk of fatal outcomes compared to that observed with SSRI antidepressant products, but lower than that for tricyclic antidepressants. Epidemiological studies have shown that venlafaxine-treated patients, is not clear. Prescriptions for Pristig should be written for the smallest quantity of capsules consistent with good patient management, in orde This brief summary is based on Pristig Prescribing Information W10529C002, revised April 2008