



**Daiichi Sankyo, Inc**  
cordially invites you to participate in a

## **Venue-based Speaker Program**

Entitled  
**AZOR®: A CCB/ARB Fixed Combination for the Treatment of  
Hypertension**

Presented By Hormaz Sanjana, MD

**Thursday, October 09, 2008**

**6:30 PM**

**Rruth's Chris Steak House - San Antonio**

1170 E Commerce St

San Antonio, TX 78205

This invitation is not transferable. In accordance with company policy and the PhRMA Code on Interactions with Healthcare Professionals, attendance at this promotional program is limited to licensed healthcare professionals. Accordingly, attendance by guests or spouses is not appropriate and cannot be accommodated.

Please RSVP to your Daiichi Sankyo representative, Lalo Madrid, by  
Monday, October 06, 2008, at 210-378-1830.

**See Page 2 for IMPORTANT SAFETY INFORMATION on this product.  
Please see full Prescribing Information for AZOR® .**



Daiichi-Sankyo

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## Important safety information

### USE IN PREGNANCY

**When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus.** When pregnancy is detected, AZOR should be discontinued as soon as possible. See **WARNINGS AND PRECAUTIONS, Fetal/Neonatal Morbidity and Mortality.**

### Hypotension in Volume- or Salt-Depleted Patients

In patients with an activated renin-angiotensin system, such as volume- and/or salt-depleted patients, symptomatic hypotension due particularly to the olmesartan component may occur after initiation of treatment with AZOR. Treatment should start under close medical supervision.

### Vasodilation

Since the vasodilation attributable to amlodipine in AZOR is gradual in onset, acute hypotension has rarely been reported after oral administration. Nonetheless, caution, as with any other peripheral vasodilator, should be exercised when administering AZOR, particularly in patients with severe aortic stenosis.

### Severe Obstructive Coronary Artery Disease

Patients, particularly those with severe obstructive coronary artery disease, may develop increased frequency, duration, or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase.

### Congestive Heart Failure

In general, calcium channel blockers should be used with caution in patients with heart failure.

### Impaired Renal Function

In studies of ACE inhibitors in patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen (BUN) have been reported. There has been no long-term use of olmesartan medoxomil in patients with unilateral or bilateral renal artery stenosis, but similar effects would be expected with AZOR because of the olmesartan medoxomil component.

### Hepatic Impairment

Since amlodipine is extensively metabolized by the liver and the plasma elimination half-life ( $t_{1/2}$ ) is 56 hours in patients with severely impaired hepatic function, caution should be exercised when administering AZOR to patients with severe hepatic impairment.

### Laboratory Tests

There was a greater decrease in hemoglobin and hematocrit in the combination product compared to either component alone.

### Adverse Reactions

The only adverse reaction that occurred in greater than or equal to 3% of patients treated with AZOR and more frequently than placebo was edema. The placebo-subtracted incidence was 5.7% (5/20 mg), 6.2% (5/40 mg), 13.3% (10/20 mg), and 11.2% (10/40 mg). The edema incidence for placebo was 12.3%.

Adverse reactions seen at lower rates but at about the same or greater incidence as in patients receiving placebo included hypotension, orthostatic hypotension, rash, pruritus, palpitation, urinary frequency, and nocturia.

In individual clinical trials of amlodipine and olmesartan medoxomil, other commonly reported adverse reactions included

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