

## DRUG DEVELOPMENT COURSE 2006

### GROUP PROJECT #1.

Hypertension is one of the most common and important risk factors for cardiovascular disease. It has been known for some time that race and ethnicity play a role in determining the risk of developing hypertension and likelihood of response to some treatments (for example thiazide diuretics). On June 23, 2005, the FDA approved BiDil® for the treatment of congestive heart failure in “self-identified black patients.” The drug has not been approved for treatment of any other racial or ethnic groups. BiDil® is a coformulation of two older approved drugs, hydralazine and isosorbide dinitrate. Development was based on findings in two earlier Phase IV trials in which this combination of drugs showed no overall benefit for CHF, but had a statistically significant benefit in African-American patients in subgroup analyses.

Your company, Ethnogene, has just finished a Phase II trial of a new anti-hypertensive drug with a unique mechanism of action. In 1000 patients of various ethnic backgrounds, there was no overall reduction in steady-state systolic or diastolic blood pressure when the new drug was added to existing Step One treatment for hypertension in patients with moderate hypertension whose blood pressure was not adequately controlled. However, a subset analysis showed a 20% mean reduction in blood pressure in the 200 patients identified as “Asian,” and this reduction was highly statistically significant ( $p < .02$ ). The company president has asked you to develop a plan to study the benefits of this drug in Asians, with the goal of submitting an NDA that will request for approval for use of this drug in this patient population only.

#### ADDRESS THE FOLLOWING:

1. Describe a Phase III trial that might meet the objectives of your company's president.
2. How will you write the “Indications” section of the package insert for such a compound?
3. What are the risks and benefits to the company of this approach to drug development?