

Circulatory System Devices Panel

Questions for Discussion 9/11/00 JUL 27 AIO :13

Novoste Beta-Cath System P000018

September 11, 2000

Evaluation of Safety and Effectiveness

Question #1

The original START protocol suggested that the institutional standard of care for antiplatelet therapy after source treatment be utilized for patients who were re-stented or received PTCA. This regimen was modified based on recommendations from the Data Safety Monitoring Board (BCST DSMB Section). A report of the antiplatelet therapy usage during the START trial is provided in the Addendum to the START Clinical Report (page 3). No incidents of stent thrombosis were reported during the START trial.

- 1. Based on this information, please discuss your recommendations for the antiplatelet therapy for patients who receive a new stent, and for patients who do not receive a new stent.**
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Question #2

Table 31 of the START Clinical Report (page 76) and the Addendum to the START Clinical Report (pages 13-35) identifies the device failures and malfunctions that occurred during the study.

- 2. Please discuss the clinical importance of the device failure and malfunction events in the evaluation of the safety and effectiveness of the Beta-Cath System.**
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Question #3

As demonstrated by the results included in Table 1 of the START Clinical Report (page 5), the incidence of the primary endpoint, target vessel failure, was significantly lower at 8 months for the treatment arm (Sr-90) compared to the placebo. The incidence of target vessel revascularization, target lesion revascularization, and major cardiac adverse events (MACE) were also significantly lower over the 8-month follow-up period for the treatment arm compared to the placebo. No incidents of stent thrombosis were detected in treatment arm, and the frequency of total occlusions was comparable between the treatment and placebo arms.

3. Please discuss whether you believe the probable clinical benefit of the radiation treatment outweighs the probable risks of death, myocardial infarction, late total occlusion, and late stent thrombosis posed by the device in the intended patient population.

Product Labeling**Question #4**

One aspect of the premarket evaluation of a new product is the review of its labeling. The labeling must indicate which patients are appropriate for treatment, identify the products potential adverse events, and explain how the product should be used to maximize benefits and minimize adverse effects. Please address the following questions regarding the product labeling (Section 4):

4a. Please comment on the INDICATIONS FOR USE section (page 12) as to whether it identifies the appropriate patient population for treatment with the device.

4b. Please comment on the CONTRAINDICATIONS section (page 12) as to whether it identifies all conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.

4c. Please comment on the WARNINGS and PRECAUTIONS sections as to whether it identifies all potential hazards regarding device use.

4d. Please discuss whether any improvements could be made to the labeling to help minimize the occurrence of device failures and malfunctions as discussed under question 2.

4e. Please comment on the remainder of the device labeling as to whether it adequately describes how the device should be used to maximize benefits and minimize adverse events.

4f. Does the panel have any other recommendations regarding the labeling of the device?

Training Program

Question #5

A summary of the Physician Training Program has been provided in the Section E, and in the Addendum to the START Clinical Report (pages 18-25).

5a. Please discuss any improvements that could be made to the training program to help minimize the occurrence of device failures and malfunctions as discussed under question 2.

5b. Please identify any other important elements that should be contained in a physicians training program for this device.

Post-Market Evaluation

Question #6

The panel pack includes the available 1-year data from the START trial (Addendum to the START Clinical Report, page 2), the available 1 - 4 year data from the BERT feasibility trial (BERT Section), and the available data from the BRIE European trial (BRIE Section).

6. Based on the clinical data provided in the panel pack, do you believe that additional clinical follow-up data or post market studies are necessary to evaluate the chronic effects of intravascular radiation administration? If so, how long should patients be followed and what endpoints and adverse events should be measured?
