# Circulatory System Devices Panel of the Medical Devices Advisory Committee

## General Issues Meeting Relating to Device Based Therapies for Hypertension

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# Disclosures

- I have nothing to disclose

# Treating Hypertension

- If BP not reduced below 150, the probability for stroke/ heart failure/ kidney failure increases
- >75% of patients require two or more medications to achieve BP control. Many patients can be on 3 to 4 drugs to control BP.
- Failure to adhere to drug-treatment or modify diet can prevent patients from achieving reduction in BP
- Approximately 3 to 4 million patients are drug resistant patients and need additional therapies to reduce BP
- 2017 ACC/AHA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults defined “Stage 1 hypertension” or mild as BP 130-39/80-89 mm Hg

# The National Cardiovascular Data Registry (NCDR®)

- NCDR comprises a suite of cardiovascular data registries
- The PVI Registry measures the prevalence, demographics, management and outcomes of patients undergoing percutaneous treatment for peripheral vascular disease — as well as carotid artery stenting (CAS) and carotid endarterectomy
- CathPCI Registry® data allows for the matching and extrapolation of medication and arterial disease prevalence to patients with documented hypertension
- The NCDR's growing base of hospitals and outpatient practices has resulted in a vast repository of clinical data.
- The NCDR's robust datasets hold answers to complex questions related to patient risk factors and outcomes; procedure and treatment trends; guidelines adherence; and device, facility and provider characteristics

# The National Cardiovascular Data Registry (NCDR®) PVI Registry

- New and Enhanced Modules for Renal Denervation Upcoming in Q1 2020
  - Modules will capture:
    - History/risk factor of renal denervation
    - Participation in clinical trial/study (yes/no)
    - Number of burns
    - Watts used
    - Location of burns
- Other modules in development for additional therapies
- Appropriate Use Criteria and Risk Adjusted Metrics in development

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# Indications and Labeling

- Role of Device Based Therapies
  - Patients that have documented adherence and failure to reduce BP following drug therapy and dietary recommendations

# Indications and Labeling

- Post-marketing Evaluation including new enrollment trials and registries
  - Post-market evaluation is key to developing sufficient evidence
  - Registries, such as NCDR®, inform treatment choices and drive quality improvement at the provider and institutional level, assist in the evaluation of practice patterns, technologies, and devices
  - Provide data to inform post-market signals

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# Clinical Study Design

- Patient Population
  - Trials need to reflect real-world patient composition (age, race, socioeconomic etc.)
  - Patient populations need to be based on real world characteristics
  - Create honest inclusion criteria to accurately measure patient populations where therapies are limited (such as limiting use of criteria based on age/co-morbidities)

# Clinical Study Design

- End Points
  - Need to show sustained and meaningful reduction in BP
  - Need to reduce cardiovascular events
  - Outcomes need to be comparable to other BP lowering clinical trials

# Benefit-Risk Profile

- Benefits for devices need to outweigh the harm
- Over a reasonable follow-up period, the interventions need to demonstrate both reduced CV events and lower rates of healthcare utilization, such as hospitalizations, compared with other treatment options or without treatment
- Need to generate sufficient evidence to generate patient-centered tools to allow for the selection of therapy based on the patient and their characteristics.

# Summary of Recommendations

- Devices need to show sustained and meaningful reduction in BP and cardiovascular events
- Patient populations need to match intervention populations
- Post-market evaluation through observational studies, including registries, is necessary


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