



FY 2016 IPPS New Technology Add-on Town Hall Meeting

Tuesday, February 3, 2014 [9a.m. to 1p.m.]

[*Each presentation will consist of a 15 minute presentation and a 5 minute Q&A session.]

- 8:30-9:00a: Meeting Registration
- 9:00-9:10a: Opening Remarks
- 9:10-9:20a: Comments from Public
- 9:20-9:40a: **Idarucizumab**, Drug (No trade name yet)
Boehringer Ingelheim Pharmaceuticals, Inc.
*** Presenter: Dr. Richard Bernstein**
- 9:40-10:00a: **DIAMONDBACK 360[®]** Coronary Orbital Atherectomy System (OAS)
Cardiovascular Systems, Inc.
***Presenter: Dr. Arthur Lee of the Cardiac and Vascular Institute of Gainesville, FL.**
- 10:00-10:10a: *Break*
- 10:10-10:30a: **CEFTAZIDIME AVIBACTAM**, Drug (Brand name to be announced upon approval) Actavis, Inc.
*** Presenter: Ian Critchley, PhD, Vice President, Clinical Microbiology at Cerexa, Inc. (a subsidiary of Actavis)**
- 10:30-10:50a: **AngelMed Guardian[®]** implantable ischemia detection system
Angel Medical Systems, Inc
*** Presenter: Dr. C. Michael Gibson**
- 10:50-11:10a: **Blinatumomab** a new class of molecular constructs called bi-specific T-cell engagers (BiTE[®]).
(BLINCYTO[™] is the Trade Brand)
Amgen Inc.
*** Presenter: Dr. Tapan Maniar**

- 11:10-11:30a: **Isavuconazole** (CRESEMBA is the Trade Brand)
Astellas Pharma
*** Presenter: Dr. Tawanda Gumbo of Baylor University Medical Center**
- 11:30-11:35a: *Break*
- 11:35-12:05p: **Drug Coated Balloon for Peripheral Angioplasty**
[The **IN.PACT™** Admiral TM Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter is the Trade Brand]
Medtronic, Inc.
*** Presenter: Dr. Gary Ansel**
Drug-Coated Balloon PTA Catheter is a guidewire-compatible, over the wire (OTW) catheter with a paclitaxel antiproliferative coating on the balloon surface available in several working lengths.
(Trade Brand is **LUTONIX®** Drug-Coated Balloon PTA Catheter)
CR Bard, Inc.
***Presenter: : Dr. Gary Ansel**
- 12:05-12:25p: VERASENSE™ Knee Balancer System
OrthoSensor, Inc.
***Presenter: Dr. Gregory J. Golladay, MD**
- 12:25-12:45p: WATCHMAN® Left Atrial Appendage (LAA) Closure Technology
Trade Brand is WATCHMAN®
Boston Scientific Corporation
***Presenter: Kenneth Stein, Senior VP,**
Chief Medical Officer-Rhythm Management, Boston Scientific, St. Paul, MN
- 12:45-1:00p:** **Wrap-up and Conclusion**

Times are Subject to Change

Public Comments on Substantial Clinical Improvement for Pending FY 2016 Applications:

Written comments for consideration in the Inpatient Prospective Payment System proposed rule may be sent to CMS via email to newtech@cms.hhs.gov or mail at the following address: Att: New Technology; Mail stop C4-08-06, 7500 Security Boulevard, Baltimore, MD 21244. All comments **must be received by Tuesday, February 24, 2015.**