Webcast Presentation Agenda

• EINSTEIN PE Clinical Trial Data Summary
  – Dr. Paul Burton, Vice President & Franchise Medical Leader, Cardiovascular & Metabolics, Janssen Research & Development, LLC

• Perspectives on XARELTO® in ORS and NVAF
  – Vanessa Broadhurst, President of Internal Medicine, Janssen Pharmaceuticals, Inc.
“Safe Harbor” Statement

This webcast contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The viewer is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, Janssen Pharmaceuticals, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; impact of business combinations; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; increased scrutiny of the health care industry by government agencies; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; manufacturing difficulties or delays; and product efficacy or safety concerns resulting in product recalls or regulatory action. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson’s Annual Report on Form 10-K for the fiscal year ended January 1, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Johnson & Johnson, Janssen Research & Development, LLC and Janssen Pharmaceuticals, Inc. do not undertake to update any forward-looking statements as a result of new information or future events or developments.
Rivaroxaban

- Specific, direct factor Xa inhibitor
- High oral bioavailability
- Rapid onset of action
- Half-life: 7–11 hours
- Dual mode of elimination:
  - One-third of drug excreted unchanged by the kidneys
  - Two-thirds of drug metabolized by the liver: half excreted renally; half excreted via the hepatobiliary route
- Phase II dose-finding studies indicated that for VTE treatment a regimen consisting of rivaroxaban 15 mg twice daily for 3 weeks followed by rivaroxaban 20 mg once daily for the subsequent period appeared most optimal
## Rivaroxaban
Developed to Reduce Thrombosis Risk in Diverse Settings

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>INDICATION</th>
<th>DOSING</th>
<th>TRIAL DESIGN</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>RECORD</td>
<td>VTE Prevention in patients undergoing total hip or knee replacement</td>
<td>10mg QD for 35 days (hip) or 14 days (knee)</td>
<td>&gt;12,500 patients in four studies vs. enoxaparin or enoxaparin / placebo combo</td>
<td>Approved</td>
</tr>
<tr>
<td>ROCKET AF</td>
<td>Prevention of stroke and systemic embolism in patients with atrial fibrillation</td>
<td>20mg QD – (15 mg QD in patients with moderate renal insufficiency)</td>
<td>~14,000 patients vs. warfarin</td>
<td>Approved</td>
</tr>
<tr>
<td>MAGELLAN</td>
<td>VTE Prevention in hospitalized acute medically ill patients</td>
<td>10mg QD for 35 days</td>
<td>~8,000 patients vs. enoxaparin</td>
<td>Study Complete: No filing planned</td>
</tr>
<tr>
<td>ATLAS ACS TIMI 51</td>
<td>Secondary prevention of cardiovascular events in patients with acute coronary syndrome</td>
<td>5-10 mg QD (in 2 divided doses)</td>
<td>~15,500 patients vs. placebo on background of standard of care</td>
<td>sNDA Filed Action Date: 2Q2012</td>
</tr>
<tr>
<td>EINSTEIN</td>
<td>Treatment and long-term secondary prevention of VTE</td>
<td>15 mg BID day 1-21; 20mg QD for 3, 6 or 12 months</td>
<td>~9,000 patients in three studies vs. enoxaparin + warfarin</td>
<td>Study Complete: Anticipated Filing: 2Q2012</td>
</tr>
</tbody>
</table>
The Need in Thrombosis Management

• More than 20 million people in the US are at elevated risk of thrombosis

• Low awareness of preventable risk
  – More patient-friendly options are needed
  – Better adherence and compliance
  – Improved protection with acceptable safety
  – Faster onset of action
  – Fewer food and drug interactions versus standard of care
  – Elimination of blood monitoring
  – Good tolerability

1. Includes MI, HF, A Fib, THR/TKR, Prior PE/DVT derived from Heart Disease and Stroke Statistics 2009 Update, accessed at http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.108.191261
**EINSTEIN Study Program**

**Confirmed DVT without symptomatic PE**

- **Day 1**
  - N=3,449
  - Rivaroxaban 15 mg bid

- **Day 21**
  - Rivaroxaban 20 mg od

**Confirmed PE ± symptomatic DVT**

- **Day 1**
  - N=4,833
  - Enoxaparin bid for at least 5 days + VKA INR 2.5 (INR range 2–3)

**Symptomatic DVT or PE completing 6 or 12 months of rivaroxaban or VKA**

- **Day 1**
  - N=1,197
  - Rivaroxaban 20 mg od

- **30-day post-study treatment period**

**Predefined treatment period of 3, 6, or 12 months**

- **Day 1**
  - Rivaroxaban 20 mg od

- **Predefined treatment period of 6 or 12 months**

- **30-day post-study treatment period**
EINSTEIN PE: Study Design

Randomized, open-label, event-driven, non-inferiority study

- Up to 48 hours of heparin/fondaparinux treatment permitted before study entry
- 88 primary efficacy outcomes needed
- Non-inferiority margin: 2.0

Objectively confirmed PE ± DVT

**Predefined treatment period of 3, 6, or 12 months**

- **Day 1**
  - Rivaroxaban 15 mg bid
  - Enoxaparin bid for at least 5 days, plus VKA INR 2.5 range 2.0–3.0

- **Day 21**
  - Rivaroxaban 20 mg od

**30-day post-study treatment period**

**Primary efficacy outcome:** first recurrent VTE

**Principal safety outcome:** first clinically relevant major or non-major bleeding
# EINSTEIN PE: Primary Efficacy Outcome Analysis

<table>
<thead>
<tr>
<th>Outcome Description</th>
<th>Rivaroxaban (N=2419)</th>
<th>Enoxaparin/VKA (N=2413)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>(%)</td>
</tr>
<tr>
<td>First symptomatic recurrent VTE</td>
<td>50</td>
<td>(2.1)</td>
</tr>
<tr>
<td>Recurrent DVT</td>
<td>18</td>
<td>(0.7)</td>
</tr>
<tr>
<td>Recurrent DVT + PE</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Non-fatal PE</td>
<td>22</td>
<td>(0.9)</td>
</tr>
<tr>
<td>Fatal PE/unexplained death where PE can not be ruled out</td>
<td>10</td>
<td>(0.4)</td>
</tr>
</tbody>
</table>

- **Rivaroxaban superior**
- **Rivaroxaban non-inferior**
- **Rivaroxaban inferior**

\[
\text{HR} = \frac{0.75}{1.12} \quad \text{for non-inferiority (one-sided)}
\]

\[
\text{p}=0.57 \text{ for superiority (two-sided)}
\]

\[
\text{P}=0.0026 \text{ for non-inferiority (one-sided)}
\]

*Potential relative risk increase <68.4%; absolute risk difference 0.24% (-0.5 to -1.02)*
EINSTEIN PE: Principal Safety Outcome – Major or Non-Major Clinically Relevant Bleeding

<table>
<thead>
<tr>
<th>Time to event (days)</th>
<th>Cumulative event rate (%)</th>
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<tbody>
<tr>
<td></td>
<td>Rivaroxaban N=2412</td>
</tr>
<tr>
<td></td>
<td>Enoxaparin/VKA N=2405</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>30</td>
<td>0.3</td>
</tr>
<tr>
<td>60</td>
<td>0.6</td>
</tr>
<tr>
<td>90</td>
<td>1.0</td>
</tr>
<tr>
<td>120</td>
<td>2.0</td>
</tr>
<tr>
<td>150</td>
<td>3.0</td>
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<tr>
<td>180</td>
<td>4.0</td>
</tr>
<tr>
<td>210</td>
<td>5.0</td>
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<tr>
<td>240</td>
<td>6.0</td>
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<tr>
<td>270</td>
<td>7.0</td>
</tr>
<tr>
<td>300</td>
<td>8.0</td>
</tr>
<tr>
<td>330</td>
<td>9.0</td>
</tr>
<tr>
<td>360</td>
<td>10.0</td>
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</table>

<table>
<thead>
<tr>
<th>Number of patients at risk – Safety population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rivaroxaban</td>
</tr>
<tr>
<td>Enoxaparin/VKA</td>
</tr>
</tbody>
</table>

Rivaroxaban n/N (%) 249/2412 (10.3)
Enoxaparin/VKA n/N (%) 274/2405 (11.4)
HR (95% CI) 0.90 (0.76–1.07)
p-value p=0.23
EINSTEIN PE: Major Bleeding

<table>
<thead>
<tr>
<th></th>
<th>Rivaroxaban</th>
<th>Enoxaparin/VKA</th>
<th>HR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n/N (%)</td>
<td>26/2412 (1.1)</td>
<td>52/2405 (2.2)</td>
<td>0.49 (0.31–0.79)</td>
<td>p=0.0032</td>
</tr>
</tbody>
</table>

Number of patients at risk – Safety population

<table>
<thead>
<tr>
<th></th>
<th>Rivaroxaban</th>
<th>Enoxaparin/VKA</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=2412</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2412</td>
<td>2281</td>
<td>2248</td>
</tr>
<tr>
<td>2248</td>
<td>2156</td>
<td>2091</td>
</tr>
<tr>
<td>2156</td>
<td>2063</td>
<td>1317</td>
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<tr>
<td>2063</td>
<td>761</td>
<td>735</td>
</tr>
<tr>
<td>761</td>
<td>700</td>
<td>669</td>
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<tr>
<td>700</td>
<td>659</td>
<td>350</td>
</tr>
<tr>
<td>659</td>
<td>642</td>
<td>278</td>
</tr>
<tr>
<td>642</td>
<td>658</td>
<td>278</td>
</tr>
</tbody>
</table>
## EINSTEIN PE: Key Secondary & Other Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Rivaroxaban</th>
<th>Enoxaparin/VKA</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N (%)</td>
<td>n/N (%)</td>
<td></td>
</tr>
<tr>
<td>Net clinical benefit*</td>
<td>83/2419 (3.4)</td>
<td>96/2413 (4.0)</td>
<td>0.85 (0.63–1.14)</td>
</tr>
<tr>
<td>Total mortality</td>
<td>58/2419 (2.4)</td>
<td>50/2413 (2.1)</td>
<td>1.13 (0.77–1.65)</td>
</tr>
</tbody>
</table>

On-treatment

- Cerebrovascular events: 12/2412 (0.5) vs. 13/2405 (0.5)
- ACS: 15/2412 (0.6) vs. 21/2405 (0.9)

Off-treatment (+ 30 days)

- Cerebrovascular: 2/2206 (<0.1) vs. 1/2197 (<0.1)
- ACS: 3/2206 (0.1) vs. 2/2197 (<0.1)

ALT>3×ULN + bilirubin>2×ULN: 5/2355 (0.2) vs. 4/2327 (0.2)

*Primary efficacy outcome plus major bleeding
EINSTEIN PE: Conclusions

• In patients with acute symptomatic PE with or without DVT, rivaroxaban showed:
  – Non-inferiority to LMWH/VKA for efficacy: HR=1.12 (0.75–1.69); \( p=0.0026 \) for non-inferiority margin of 2.0
  – Similar findings for principal safety outcome: HR=0.90 (0.76–1.07); \( p=0.23 \)
  – Superiority for major bleeding: HR=0.49 (0.31–0.79) \( p=0.0032 \)
  – Consistent efficacy and safety results irrespective of age, body weight, gender, kidney function and cancer
  – No evidence for liver toxicity

• For more study details, visit *The New England Journal of Medicine* online at [www.nejm.org](http://www.nejm.org), or our press release on [www.jnj.com](http://www.jnj.com)
XARELTO® (rivaroxaban)
Approved US Indications

• Prevention of deep vein thrombosis (DVT) which may lead to a pulmonary embolism (PE) in people undergoing knee or hip replacement surgery.

• Reduction in the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). There are limited data on the relative effectiveness of XARELTO® and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well-controlled.
Venous Thromboembolism

• More than 800,000 people undergo knee or hip replacement surgery in U.S. each year
  – These procedures come with increased blood clot risk
  – If clot breaks off and travels to lungs, a potentially life-threatening PE can form

• XARELTO® helps physicians better protect their patients from these highly preventable surgical complications.
Nonvalvular Atrial Fibrillation

• Most common sustained cardiac rhythm disorder
  – Affects ~2.3 million people in U.S.
  – Causes irregular heart beat
  – Predisposes patient clot formation
  – Increases risk of stroke five-fold

• XARELTO® gives health care professionals and patients the only once-daily option for reducing the risk of stroke without the need for routine blood monitoring
NBRx Share in the Oral Anti-Coagulant Market

Source: IMS NPA Weekly; data through 3/9/12
XARELTO® and Dabigatran NRx Share of Novel Oral Market (All Strengths)

Source: IMS NPA Weekly; data through 3/9/12
XARELTO® and Dabigatran NRx Share of NVAF Novel Oral Market

Source: IMS NPA Weekly; data through 3/9/12
Very Favorable Formulary Access

- Majority of plans have XARELTO® in Tier 2 or Tier 3
  - Represents more than 85% of lives covered

- Medicare Part D:
  - Almost 70% of lives covered in preferred position

- Commercial plans
  - 35% of lives covered in preferred position

- Well positioned for even broader coverage by year end
Marketplace Dynamics for XARELTO®

- Different marketplace than just 18 months ago
- Many unstable warfarin patients switched early to dabigatran
  - XARELTO® NVAF indication approved more than a year later
- Competition is focused on indicated unstable patients, new starts or warfarin-stable patients
- Current market data show:
  - Steady market share growth
  - Increased demand for XARELTO® in NVAF and orthopedic surgery indications
Robust Pipeline for XARELTO®

• 2 approvals in 2011 (ORS, NVAF)
• 1 expected decision in 2Q12 (secondary prevention of acute coronary syndrome) – FDA priority review status
• 1 expected filing in 2Q12 (VTE treatment)
• Strong lifecycle management program
• Confident about potential of XARELTO® in making a meaningful impact in appropriate patients over time
Questions?

• For Investor Relations Inquiries, Contact:
  – Louise Mehrotra at 732-524-6491
  – Stan Panasewicz at 732-524-2524

• For a copy of the EINSTEIN PE data press release, please visit the “News” section on the Johnson & Johnson website at www.jnj.com/connect/news/product

Thank you