LATUDA Clinical Development Update

LATUDA Meeting (Tokyo)

January 2011

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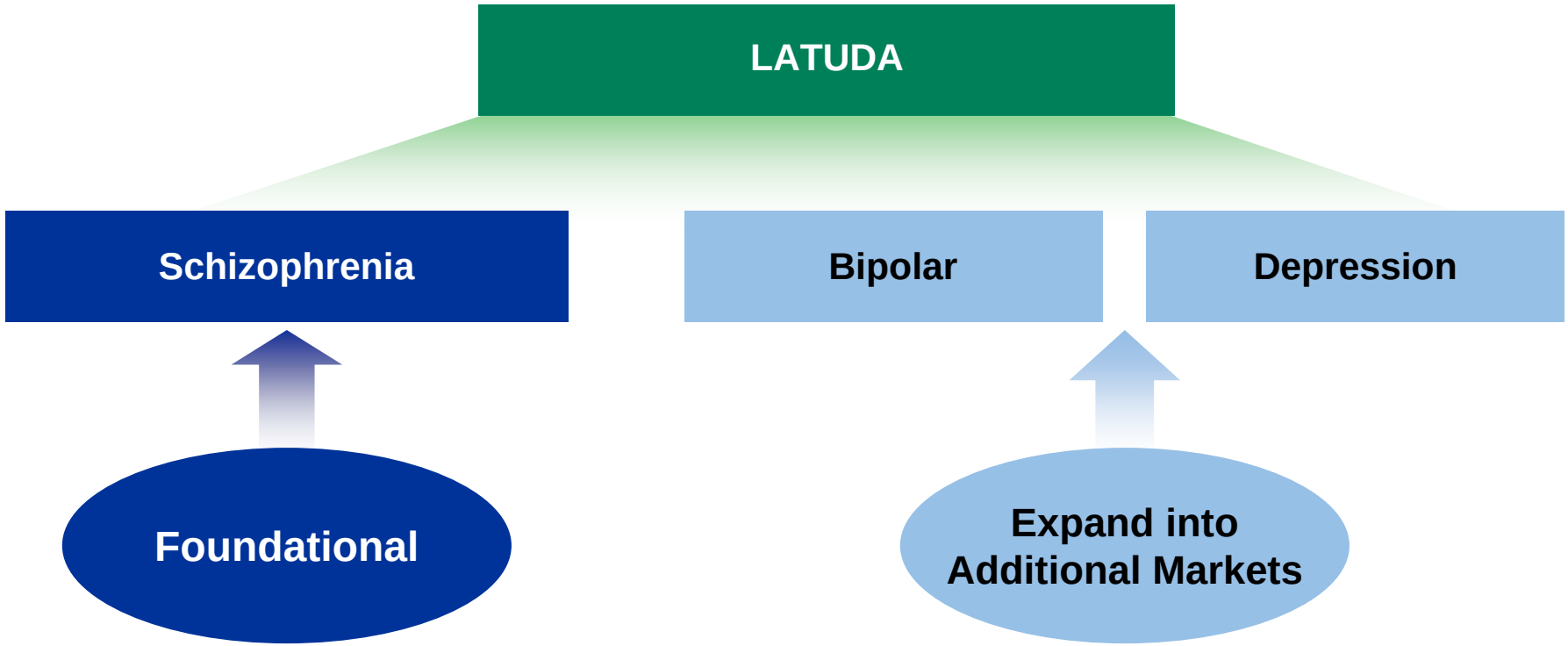
Clinical Research and Medical Affairs
Sunovion Pharmaceuticals Inc.

Agenda

- LATUDA Label Overview
  - Approval timeline
  - Label highlights
- Schizophrenia Program
  - Overview of results of PEARL studies
  - Highlights from the PEARL Safety study
  - Ongoing and planned studies in schizophrenia
- Bipolar Depression Development Program
  - Overview of PREVAIL program
- LATUDA Global Development Plan

DAINIPPON SUMITOMO PHARMA

Successfully Launch LATUDA and Maximize the Molecule Across Its Lifecycle



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LATUDA US FDA Approval

- First atypical antipsychotic to receive a first-cycle US FDA approval
- 10 Month Standard FDA Review
  - NDA filed: December 30, 2009
  - FDA Approval: October 28, 2010
- One of only 21 products approved by the FDA in 2010
  - The only Psychiatric Products division NME approved in 2010

NEW Latuda® (lurasidone HCl) tablets 40mg and 80mg

40 mg

Size: 8 mm

80 mg

Size: 12 mm x 7 mm

Source: Bloomberg News

LATUDA Label Highlights

Label Reflects Favorable Product Profile

- Indication
  - LATUDA is indicated for the treatment of patients with schizophrenia
- Doses
  - 40 or 80 mg/d recommended, no titration needed; once daily with food (350 cal min)
- Contraindications/Warnings
  - Contraindicated for hypersensitivity to drug (angioedema case); Strong 3A4 blockers (ketoconazole) or inducers (rifampin)
  - Elderly patients with dementia-related psychosis should not be treated with atypical antipsychotics like LATUDA
  - No QTc contraindication or warning
- Other Highlights
  - Metabolic data – includes short as well as long-term data (24, 36 and 52 week) for weight, lipids and glucose
  - Data from PEARL 2 (study 231) on olanzapine is included in the efficacy and safety section of the label

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Note: Please refer to LATUDA Full Prescribing Information, 2010

LATUDA Label Highlights

Label Includes Substantial Safety and Efficacy Database

- 4 efficacy data studies included
  - Phase 2a (006): LATUDA 40 and 120 mg/d
  - Phase 2b (196): LATUDA at 80 mg/d
  - PEARL 1 (229): LATUDA at 80 mg/d
  - PEARL 2 (231): LATUDA at 40 and 120 mg/d and olanzapine
- 2,096 patients with schizophrenia exposed to one or more LATUDA doses
  - 1,004 patients treated with LATUDA in short-term placebo-controlled schizophrenia studies (doses 20-120 mg/d)
  - 533 patients treated with LATUDA for ≥24 weeks
  - 238 patients treated with LATUDA for ≥52 weeks
  - 624 patient-years total exposure

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Source: LATUDA Full Prescribing Information, 2010

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LATUDA Phase 2 and 3 Schizophrenia Trials

		LATUDA mg/d				
	N	40 mg	80 mg	120 mg	160 mg	Active Control
Study 006	149	40		120		
Study 196	180		80			
Study 229 (PEARL 1)	500	40	80	120		
Study 231 (PEARL 2)	478	40		120		Olanz 15
Study 233 (PEARL 3)	488		80		160	Quet XR 600

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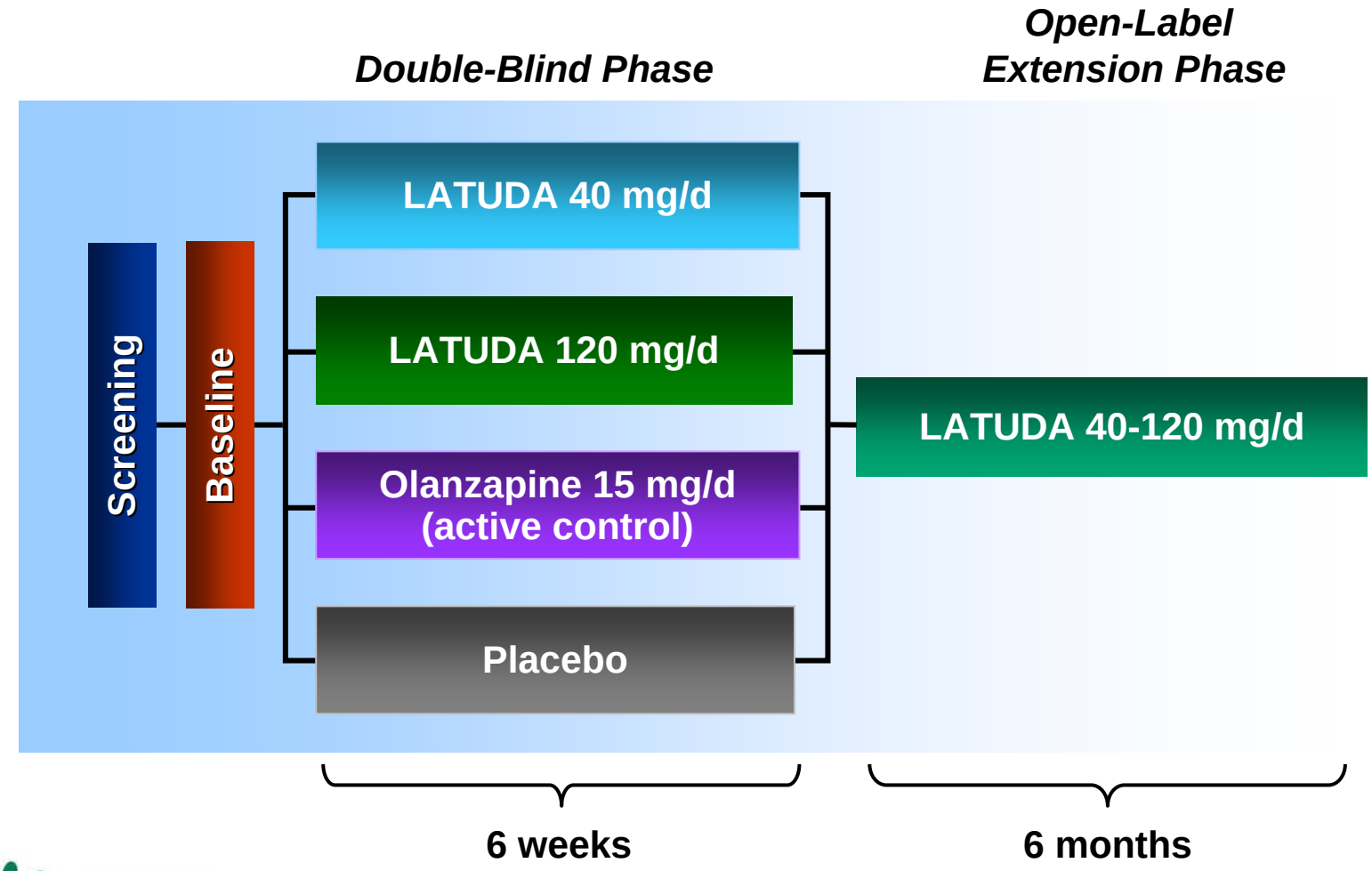
PEARL 2 (Study 231): Study Design



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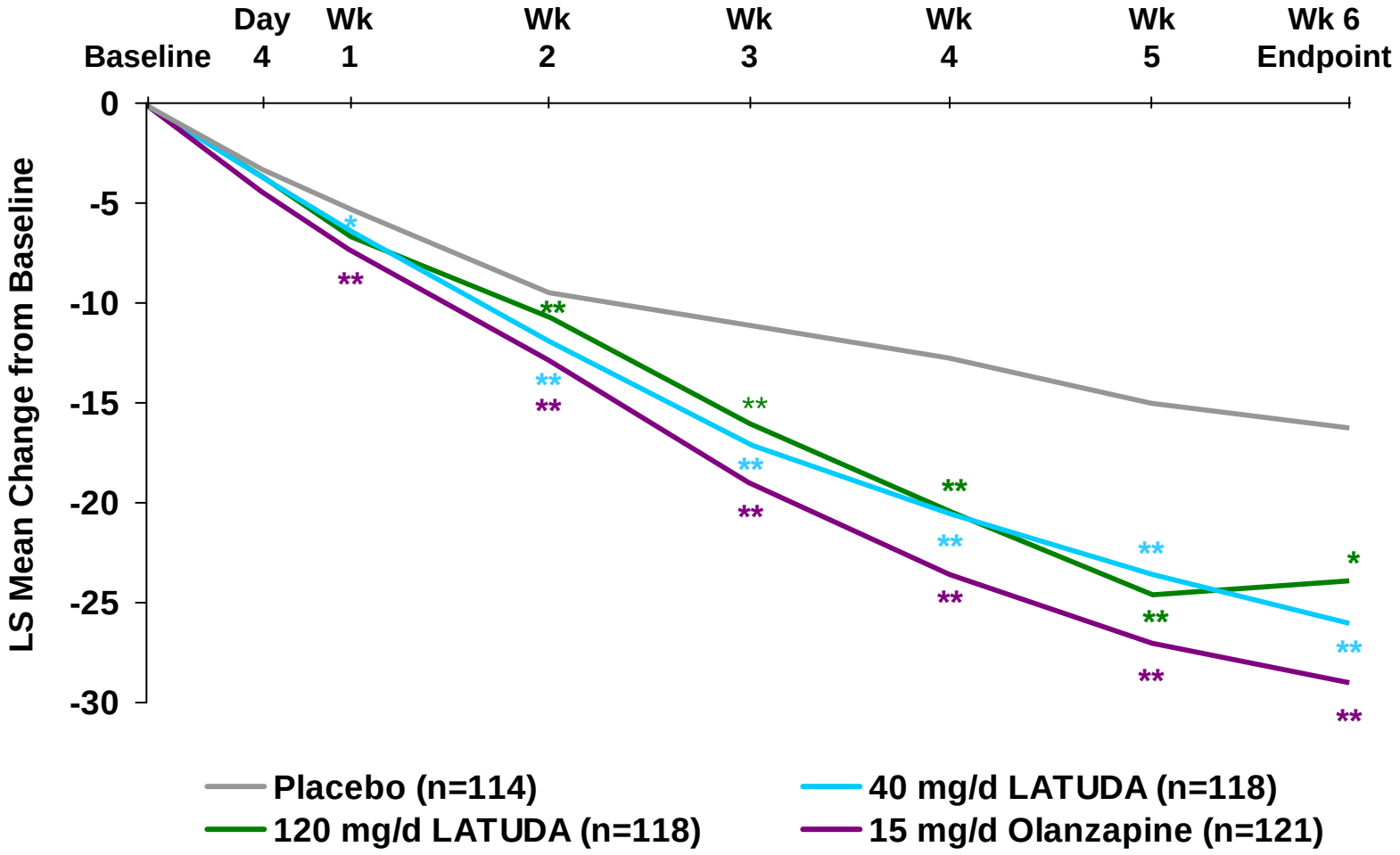
Olanzapine 15 mg/d was included as an active control for assay sensitivity
Data were analyzed using LOCF analysis

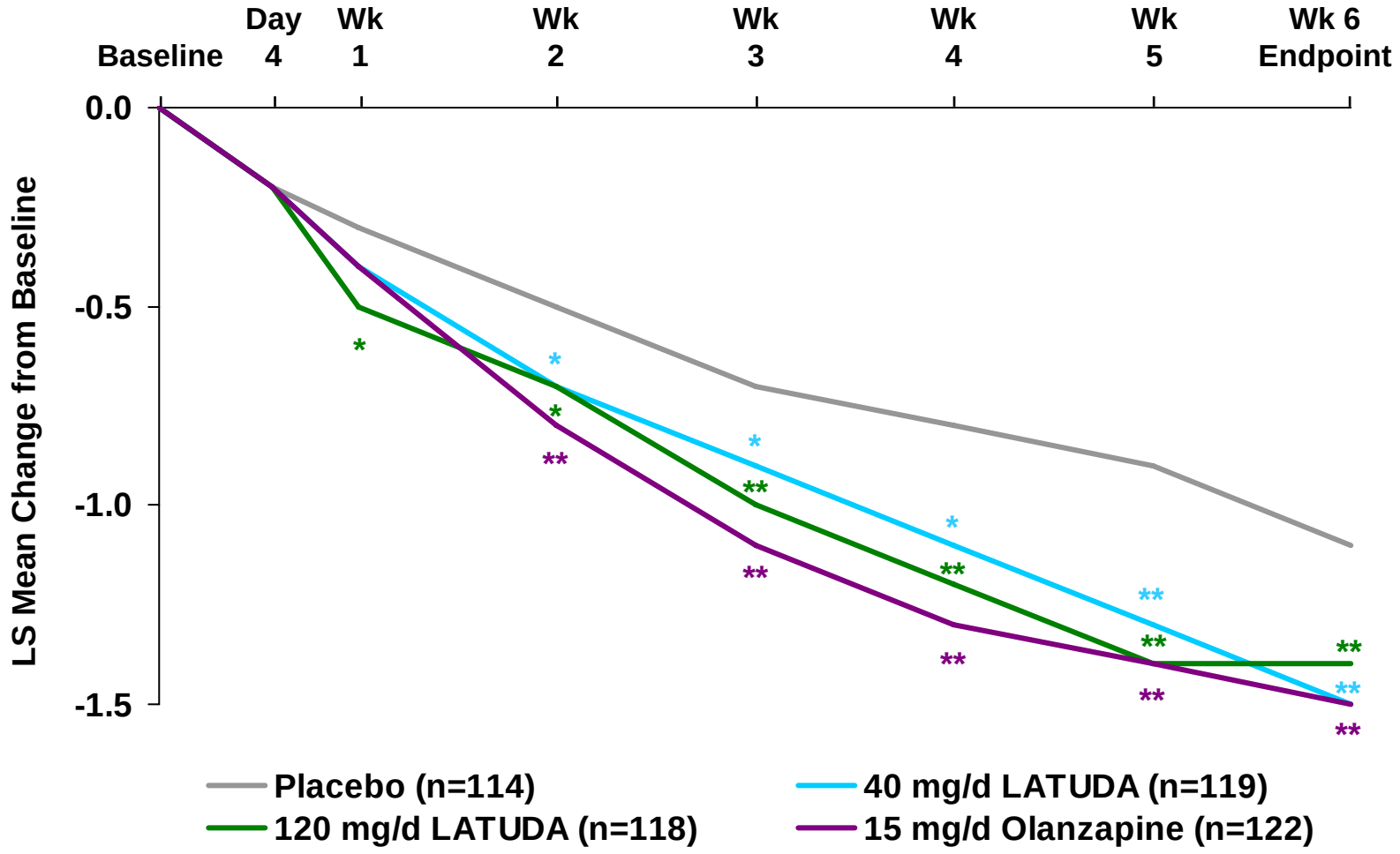
PEARL 2 Results: PANSS Total (MMRM)



*p<0.05; **p<0.01

H. Meltzer et al. Poster presented at ACNP meeting, December 2009

PEARL 2 Results: CGI-S (MMRM)



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*p<0.05; **p<0.01

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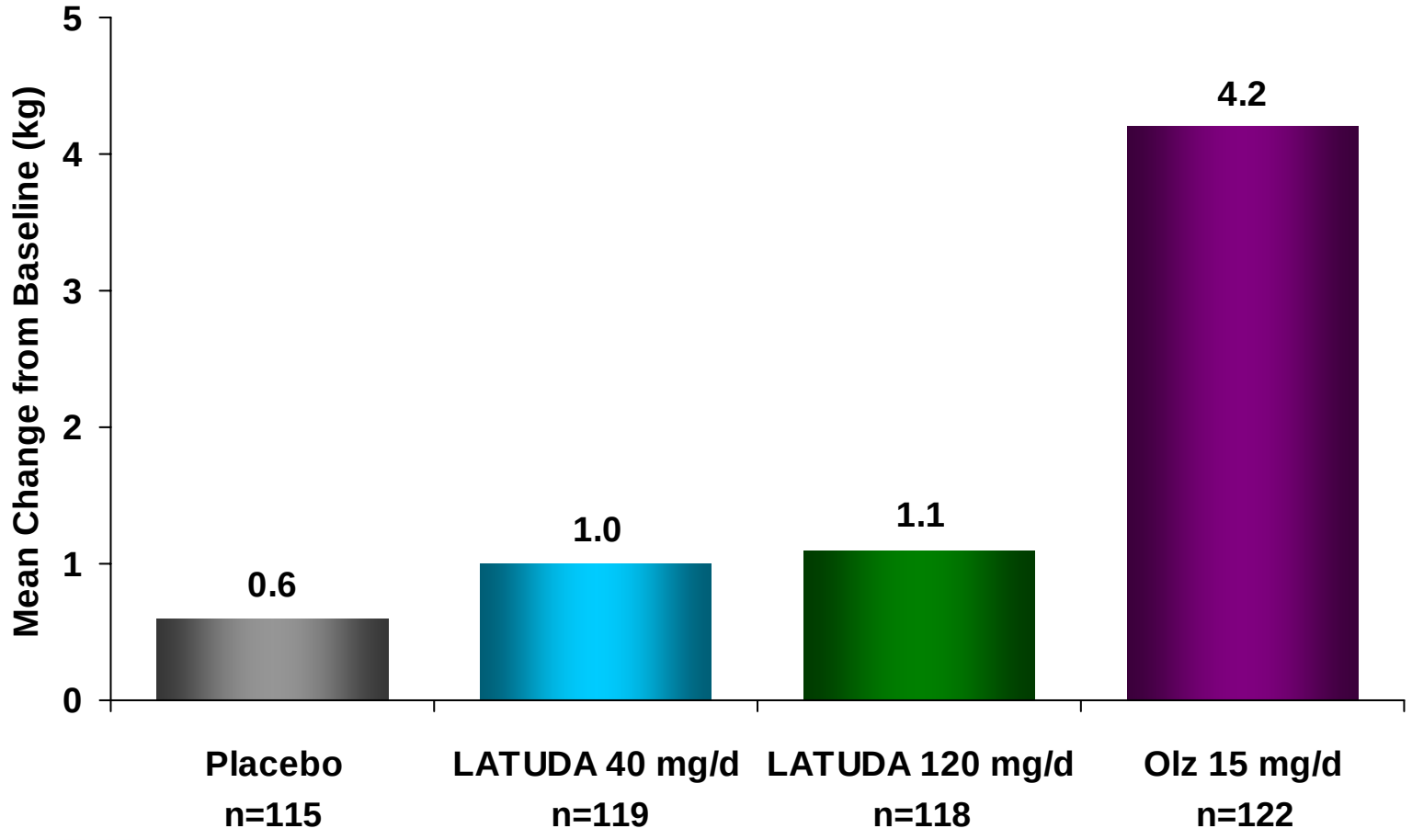
PEARL 2 Results: Weight Change (LOCF)



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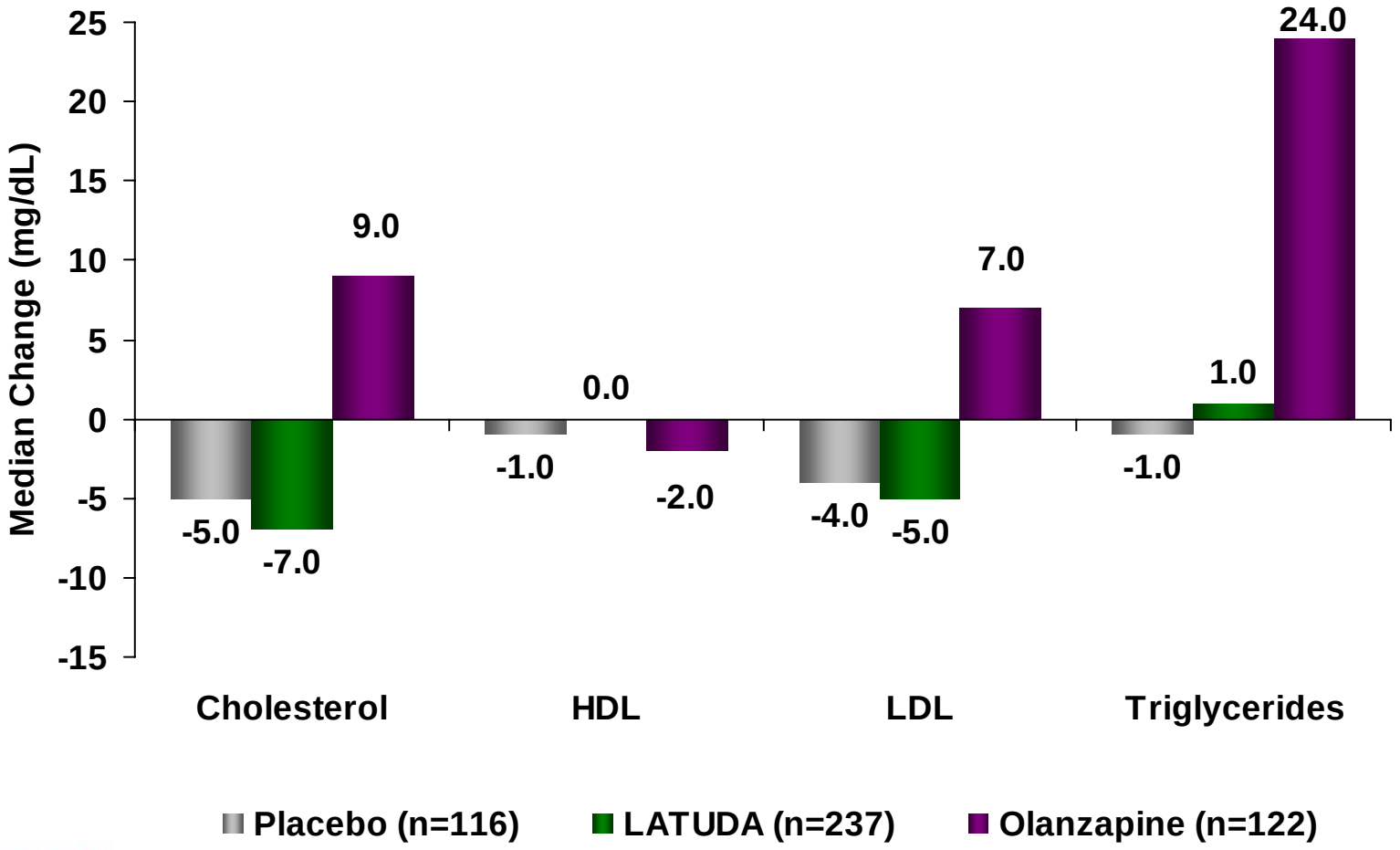
J. Meyer et al. Poster presented at ACNP meeting, December 2009

PEARL 2 Results: Lipid Profile



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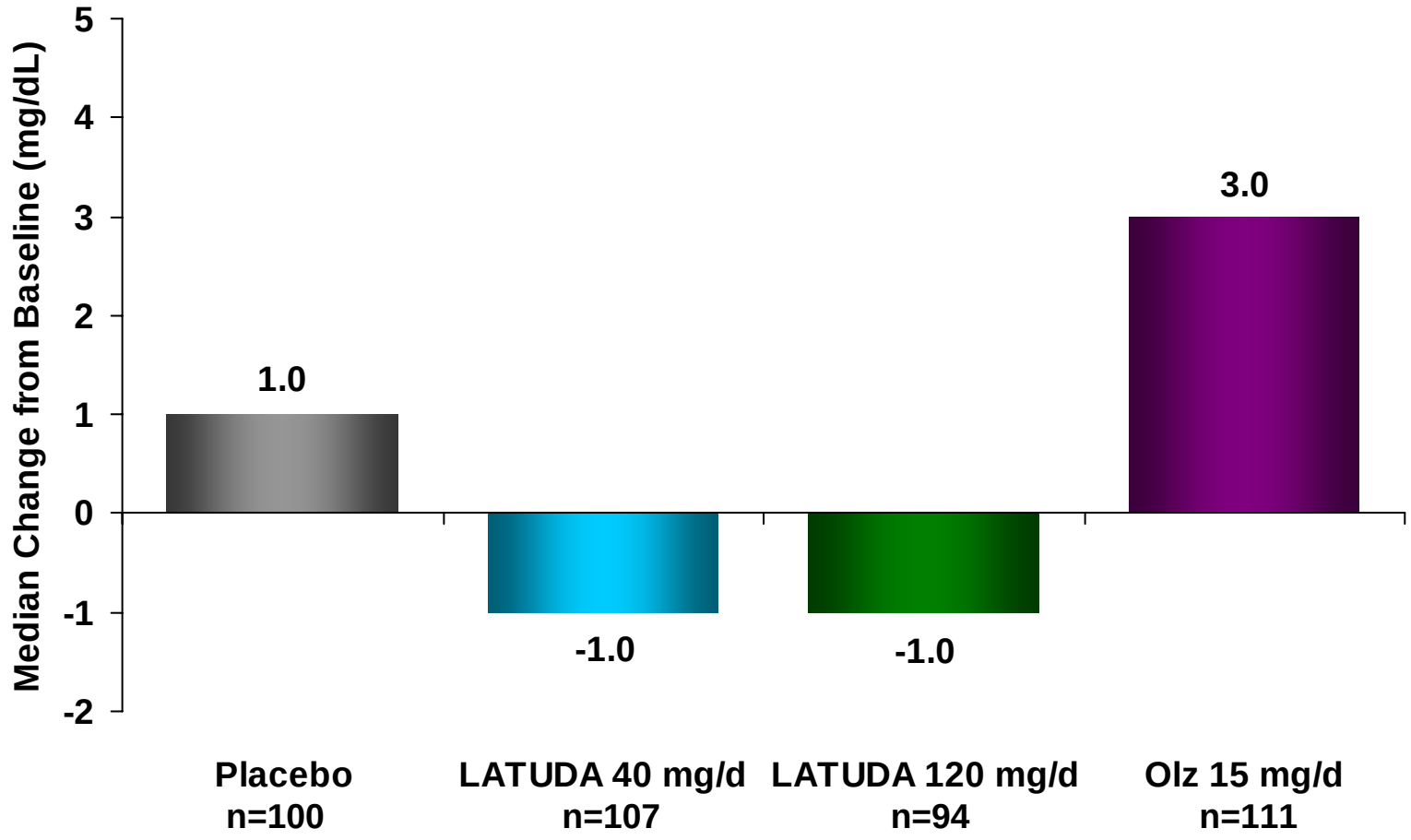
LOCF endpoint values; all subjects fasting per protocol

J Meyer et al. Poster presented at ACNP meeting, December 2009.

PEARL 2 Results: Glucose (LOCF)



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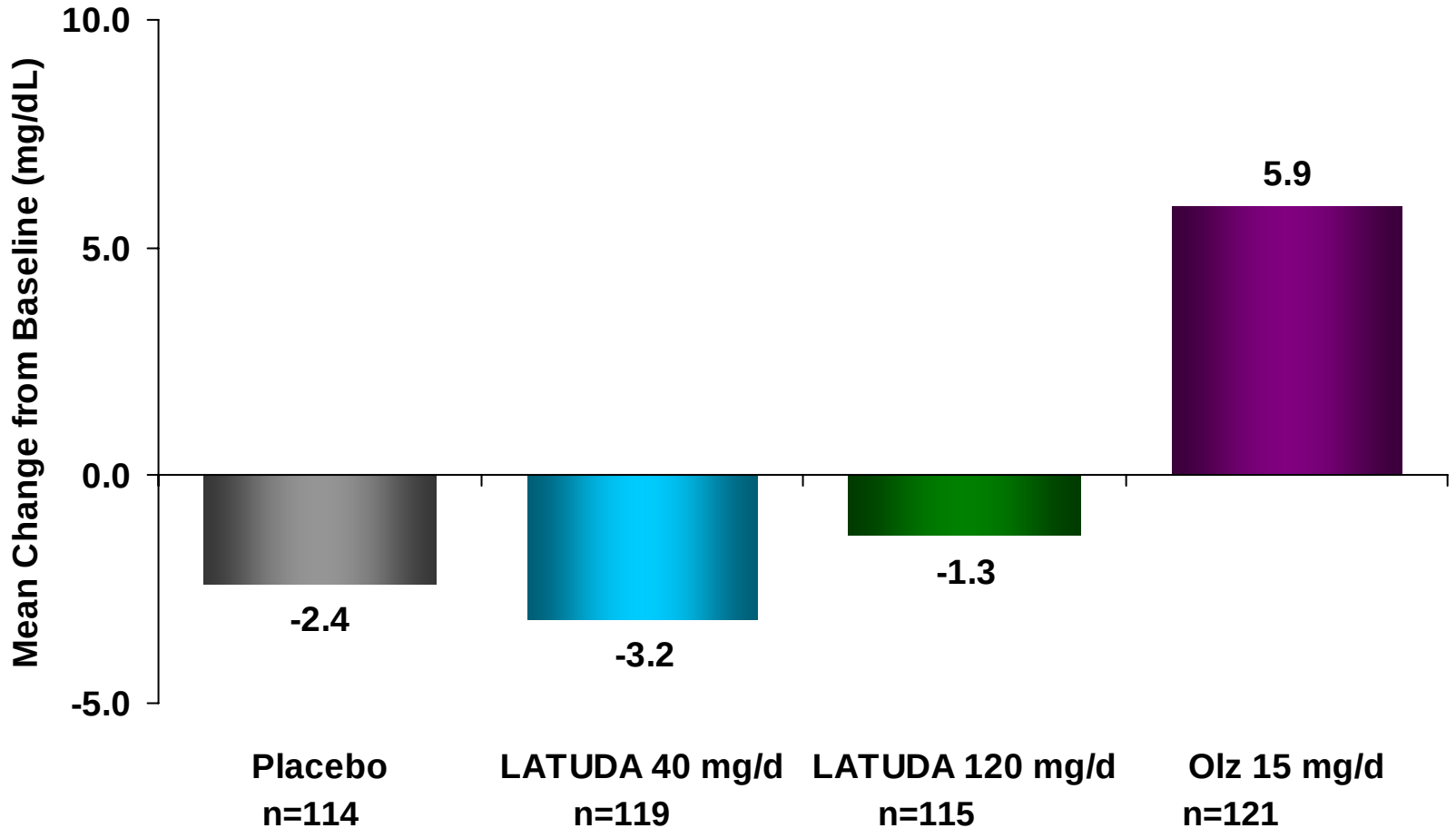
All subjects fasting per protocol

J. Meyer et al. Poster presented at ACNP meeting, December 2009.

PEARL 2 Results: Insulin (LOCF)



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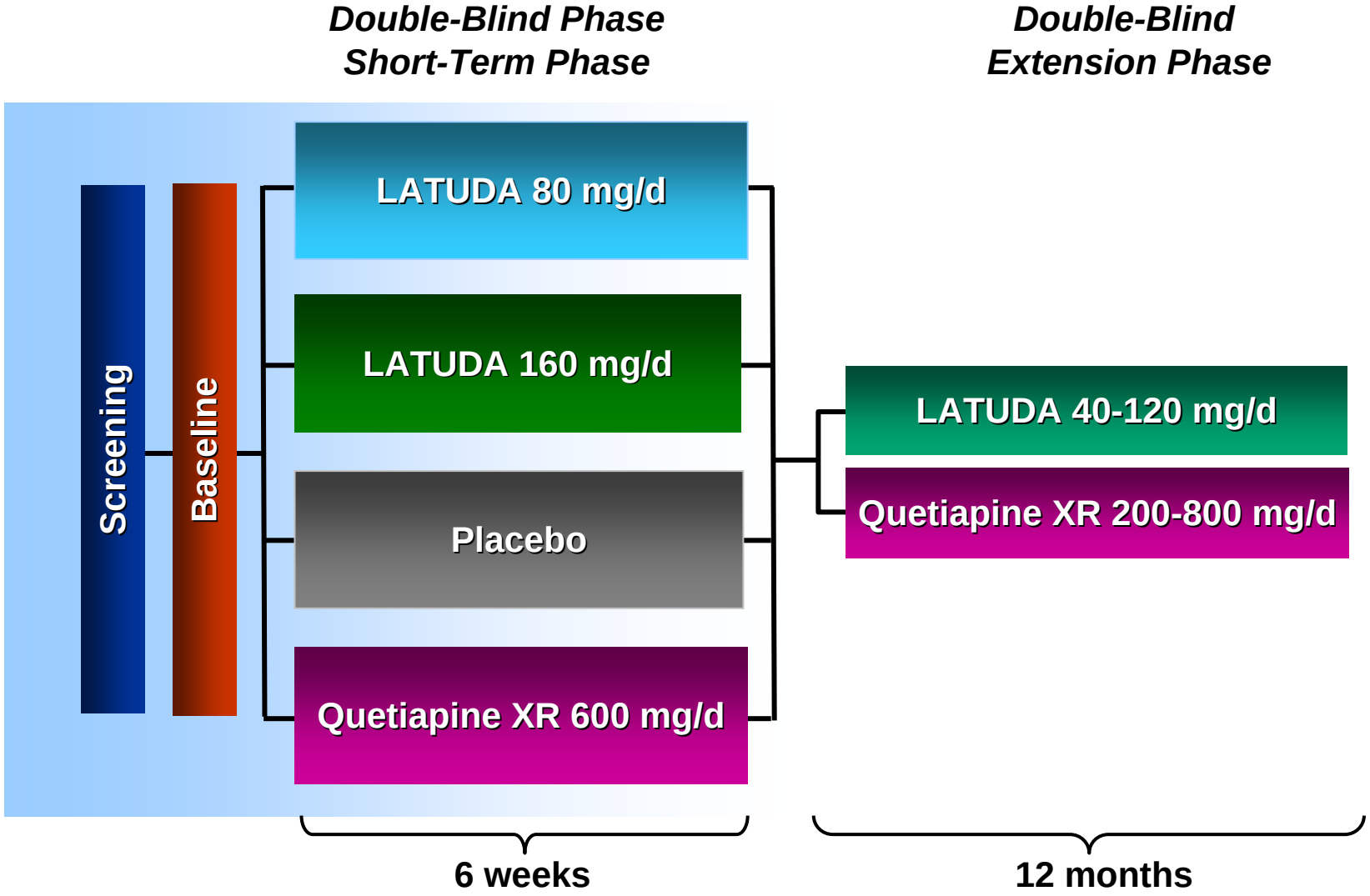
All subjects fasting per protocol

J. Meyer et al. Poster presented at ACNP meeting, December 2009.

PEARL 3:
Study Design



Note: The data for 160 mg/day dose of LATUDA have not yet been submitted to the U.S. Food and Drug Administration.
The use of quetiapine XR in the study was for the purpose of establishing assay sensitivity. Quetiapine XR is not marketed in Japan.

PEARL 3:
Subject Disposition

	LATUDA 80 mg/d	LATUDA 160 mg/d	Quet XR 600 mg/d	Placebo
Number of Subjects Randomized (n=488)	125	121	120	122
Discontinuations	36 (29%)	28 (23%)	23 (19%)	48 (39%)
Insufficient Clinical Response	16 (13%)	12 (10%)	6 (5%)	28 (23%)
Adverse Event	5 (4%)	4 (3%)	4 (3%)	5 (4%)
Withdrawal of Consent	12 (10%)	9 (7%)	13 (11%)	14 (11%)
Lost to Follow-up	1 (<1%)	1 (<1%)	0	0
Protocol Violation	1 (<1%)	0	0	0
Administrative	1 (<1%)	2 (2%)	0	1 (<1%)

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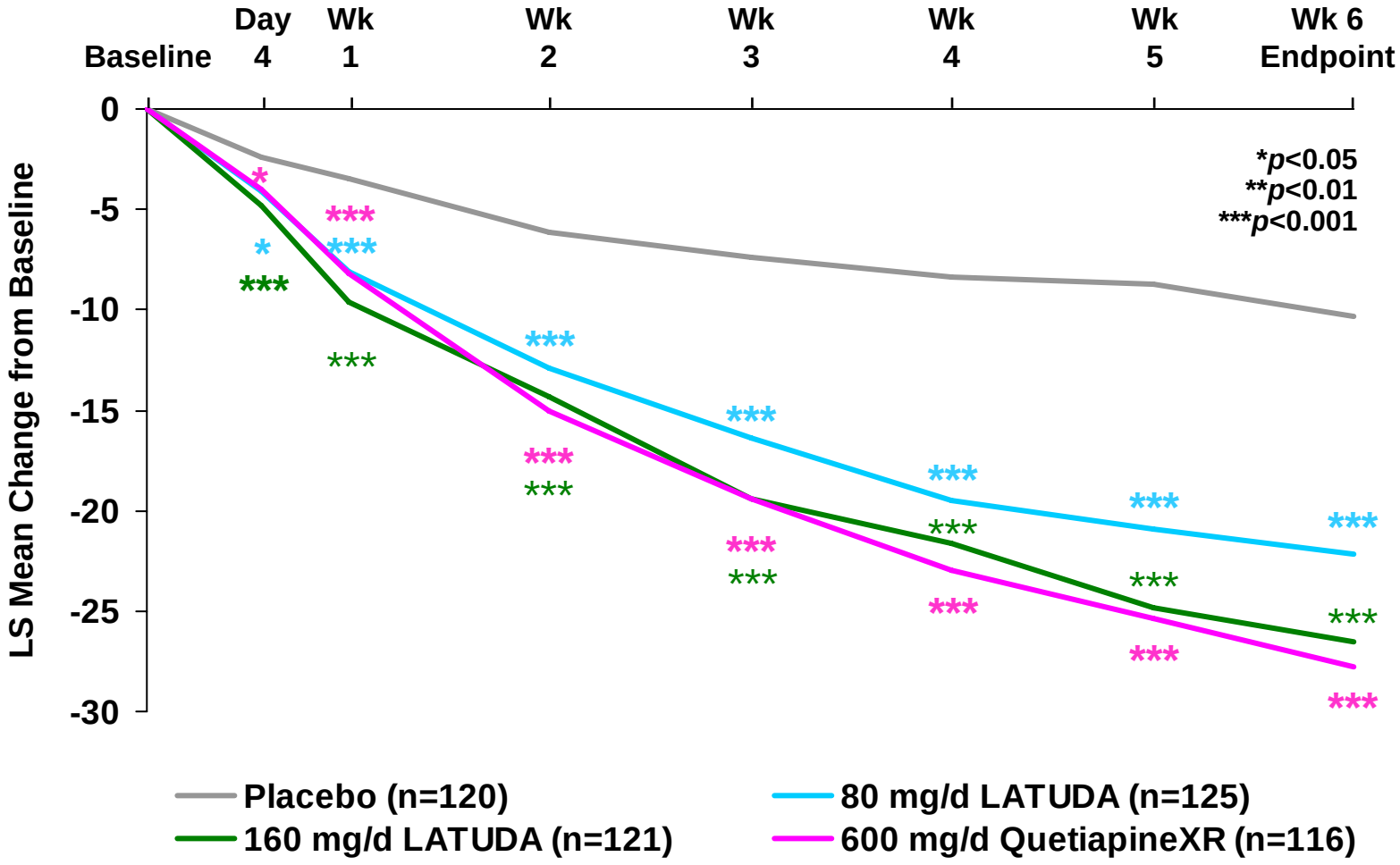
PEARL 3 Results: PANSS Total (MMRM)



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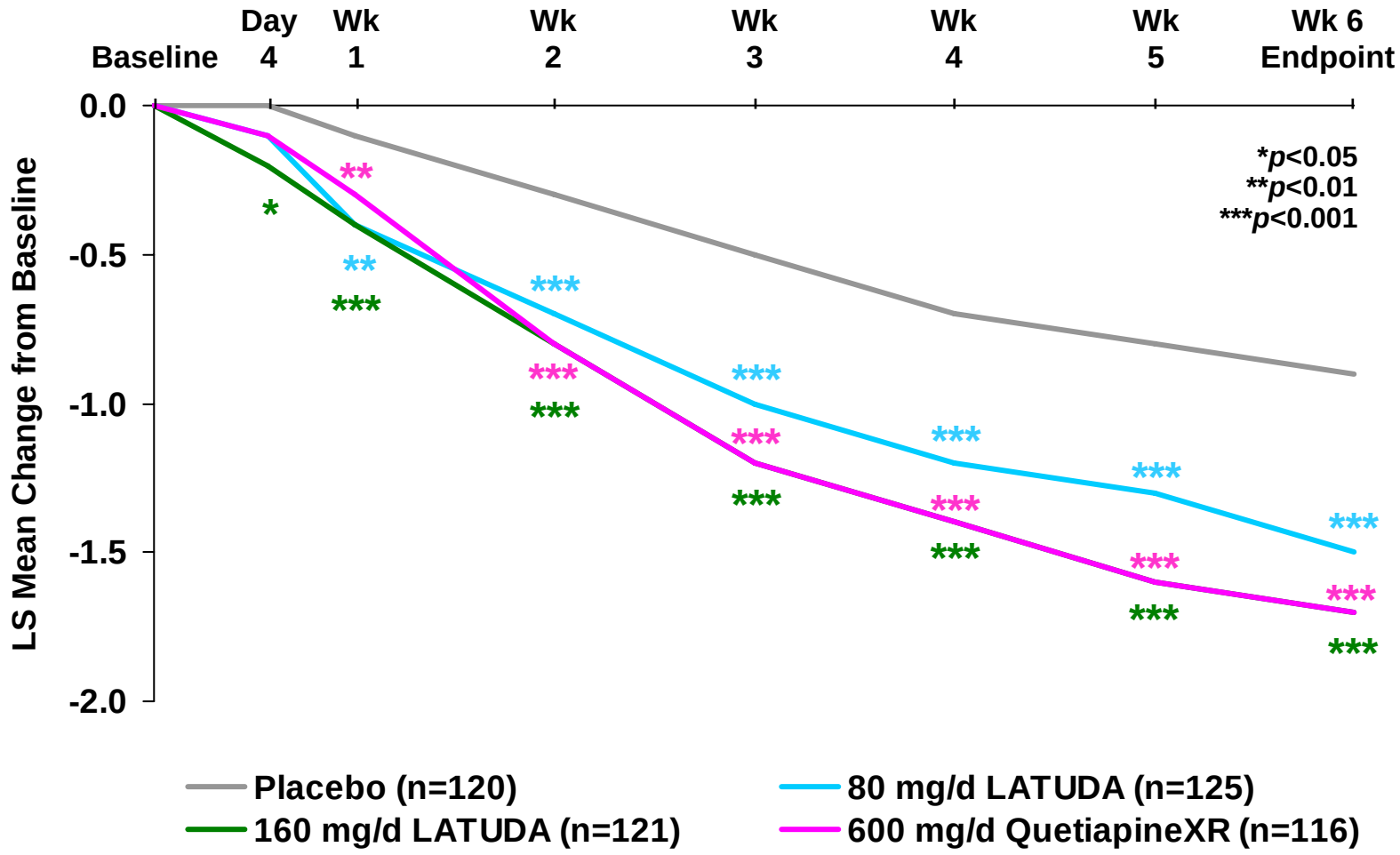
A. Loebel et al. Poster presented at ACNP meeting, Dec 8th, 2010.

PEARL 3 Results: CGI-S (MMRM)



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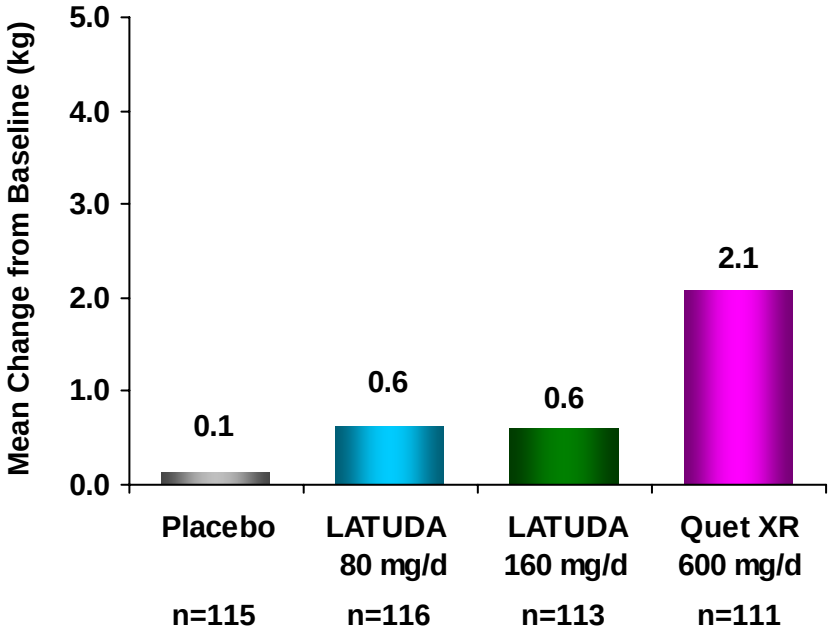
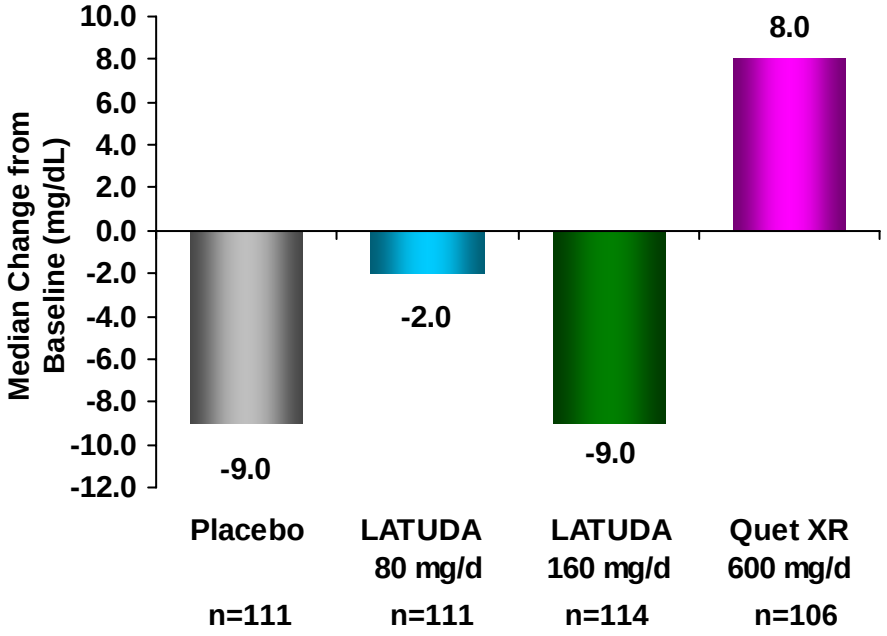
PEARL 3 Results: Metabolic

Weight Change



Triglycerides



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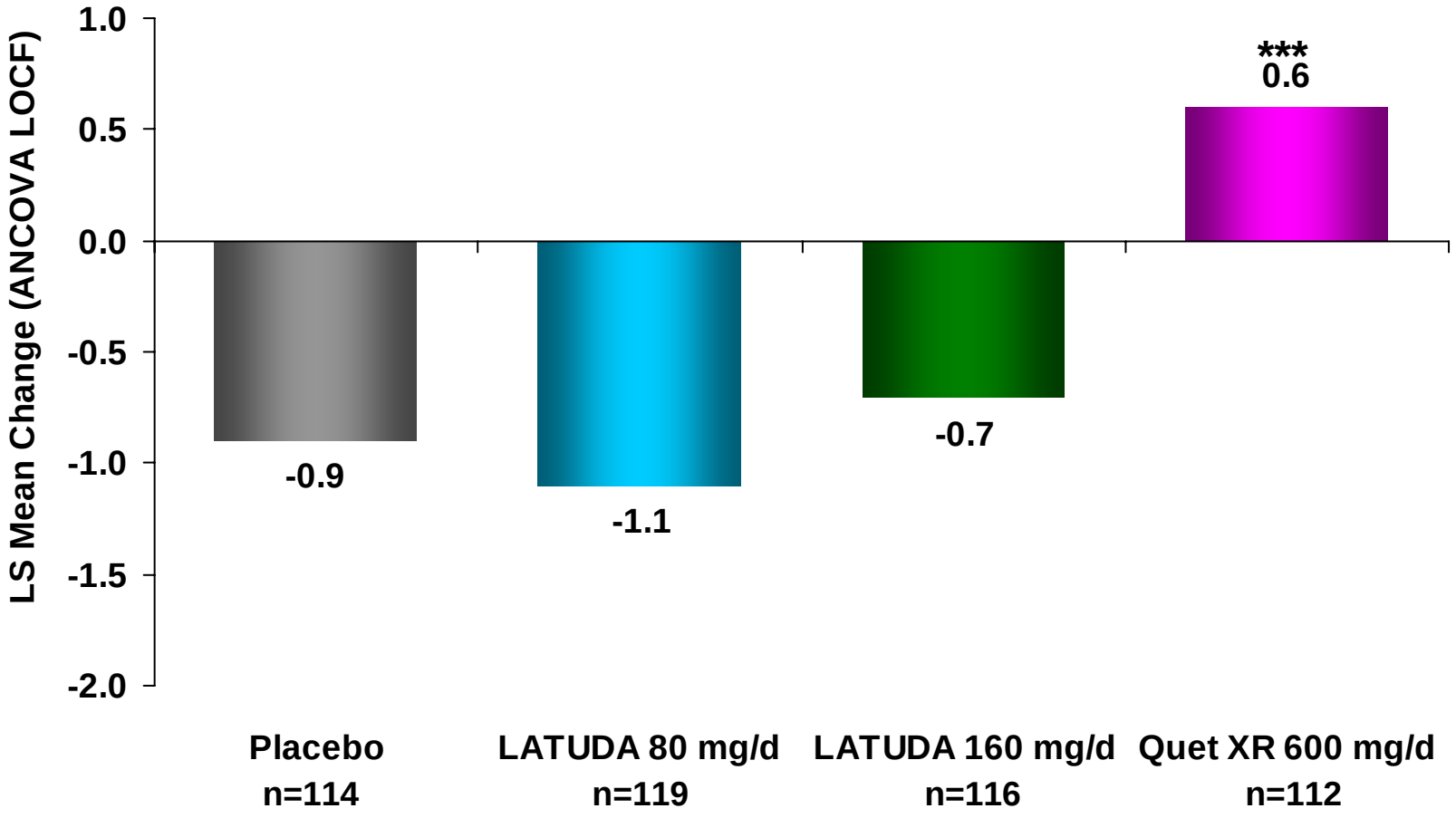
Loebel A. et al. Poster presented at ACNP meeting, Dec 8th, 2010.

PEARL 3 Results: Epworth Sleepiness Scale



DAINIPPON SUMITOMO PHARMA

A. Loebel et al. Poster presented at ACNP meeting, Dec 8th, 2010

***$p<0.001$

PEARL 3: Selected Common AEs for LATUDA and Quetiapine XR

Adverse Event	LATUDA 80 mg/d (n=125)	LATUDA 160 mg/d (n=121)	Quet XR 600 mg/d (n=119)	Placebo (n=121)
Akathisia	10 (8.0%)	9 (7.4%)	2 (1.7%)	1 (0.8%)
Nausea	10 (8.0%)	9 (6.6%)	4 (3.4%)	4 (3.3%)
Parkinsonism	7 (5.6%)	8 (6.6%)	4 (3.4%)	0
Dizziness	6 (4.8%)	7 (5.8%)	16 (13.4%)	2 (1.7%)
Somnolence	5 (4.0%)	8 (6.6%)	16 (13.4%)	1 (0.8%)
Dry Mouth	2 (1.6%)	2 (1.7%)	9 (7.6%)	1 (0.8%)
Constipation	3 (2.4%)	1 (0.8%)	8 (6.7%)	3 (2.5%)
Weight Increased	1 (0.8%)	2 (1.7%)	8 (6.7%)	1 (0.8%)

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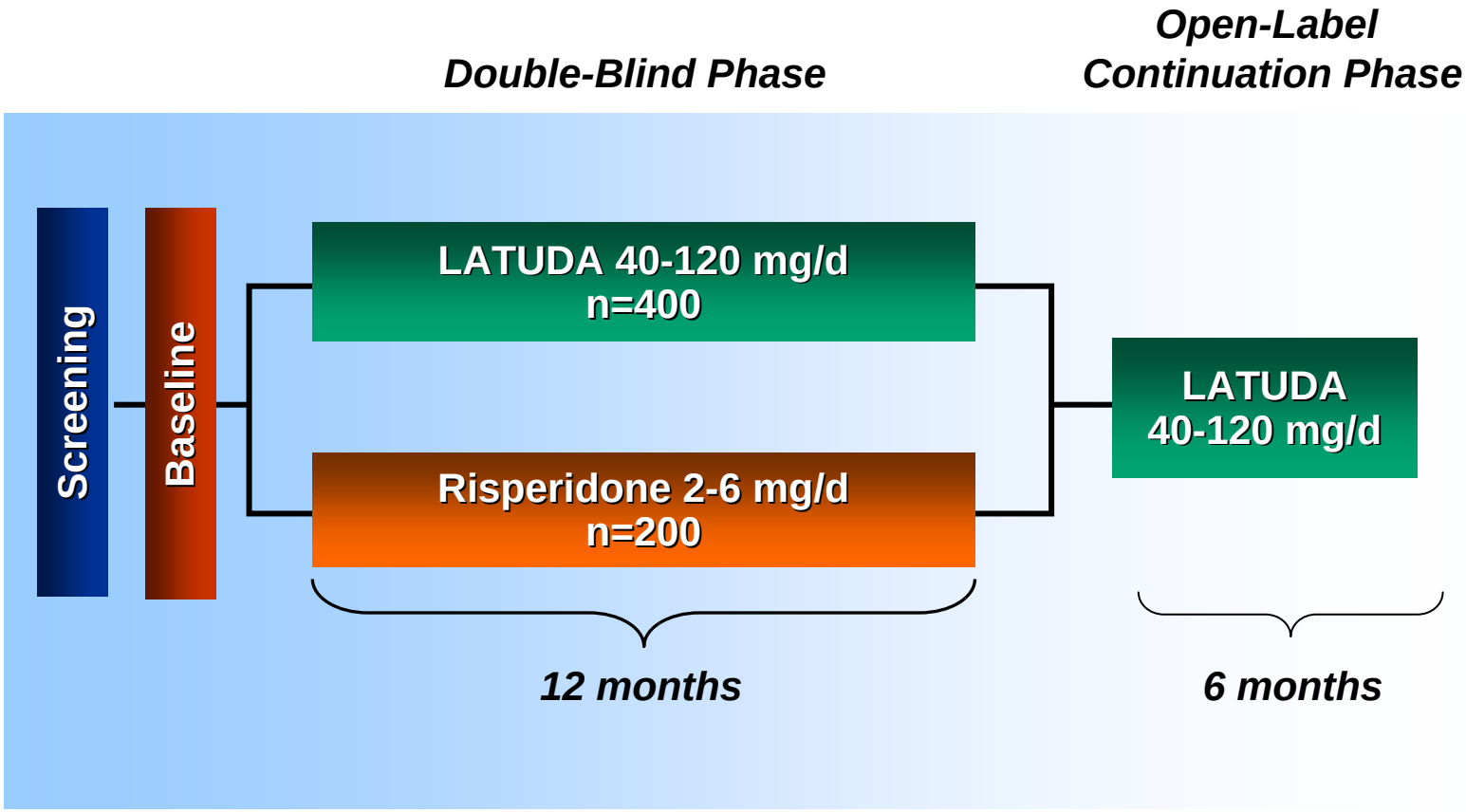
PEARL Safety trial (LTSS: Long Term Safety Study): Study design



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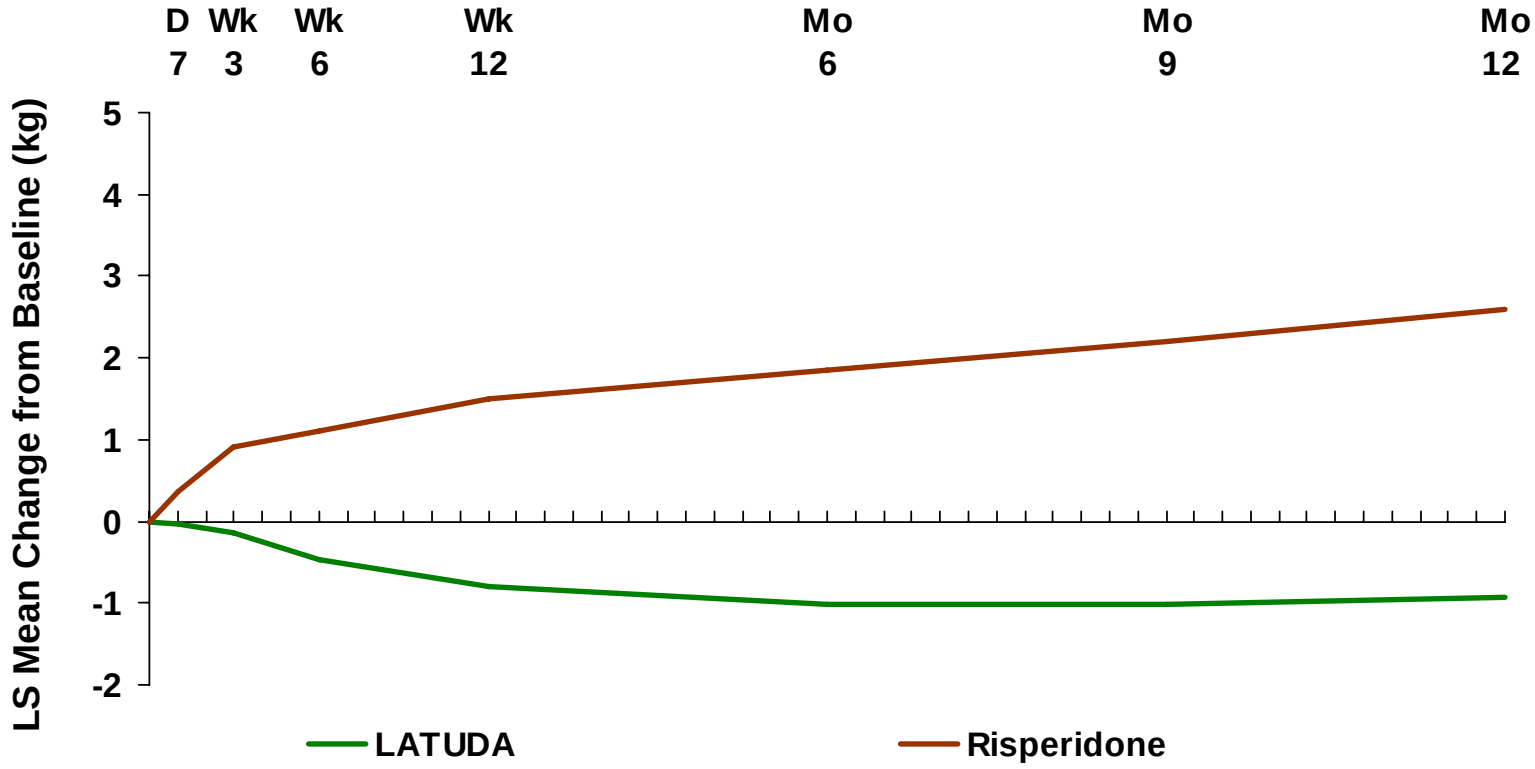
LTSS Safety Results: Weight Change (Observed Case)



		BL	Day 7	Wk 3	Wk 6	Wk 12	Mo 6	Mo 9	Mo 12
LATUDA	n =	419	406	359	337	282	216	173	150
Risperidone	n =	202	196	175	162	135	122	106	98

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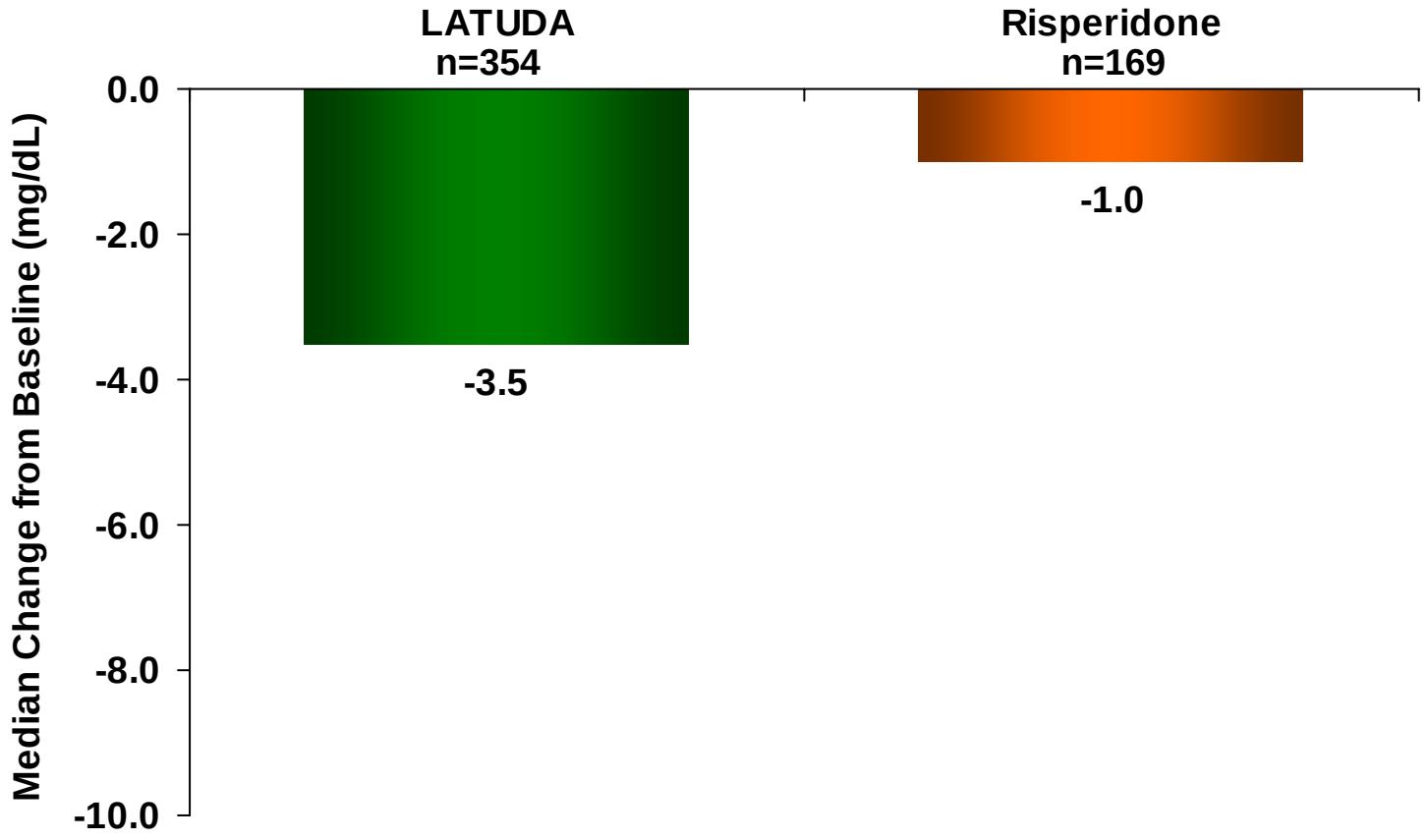
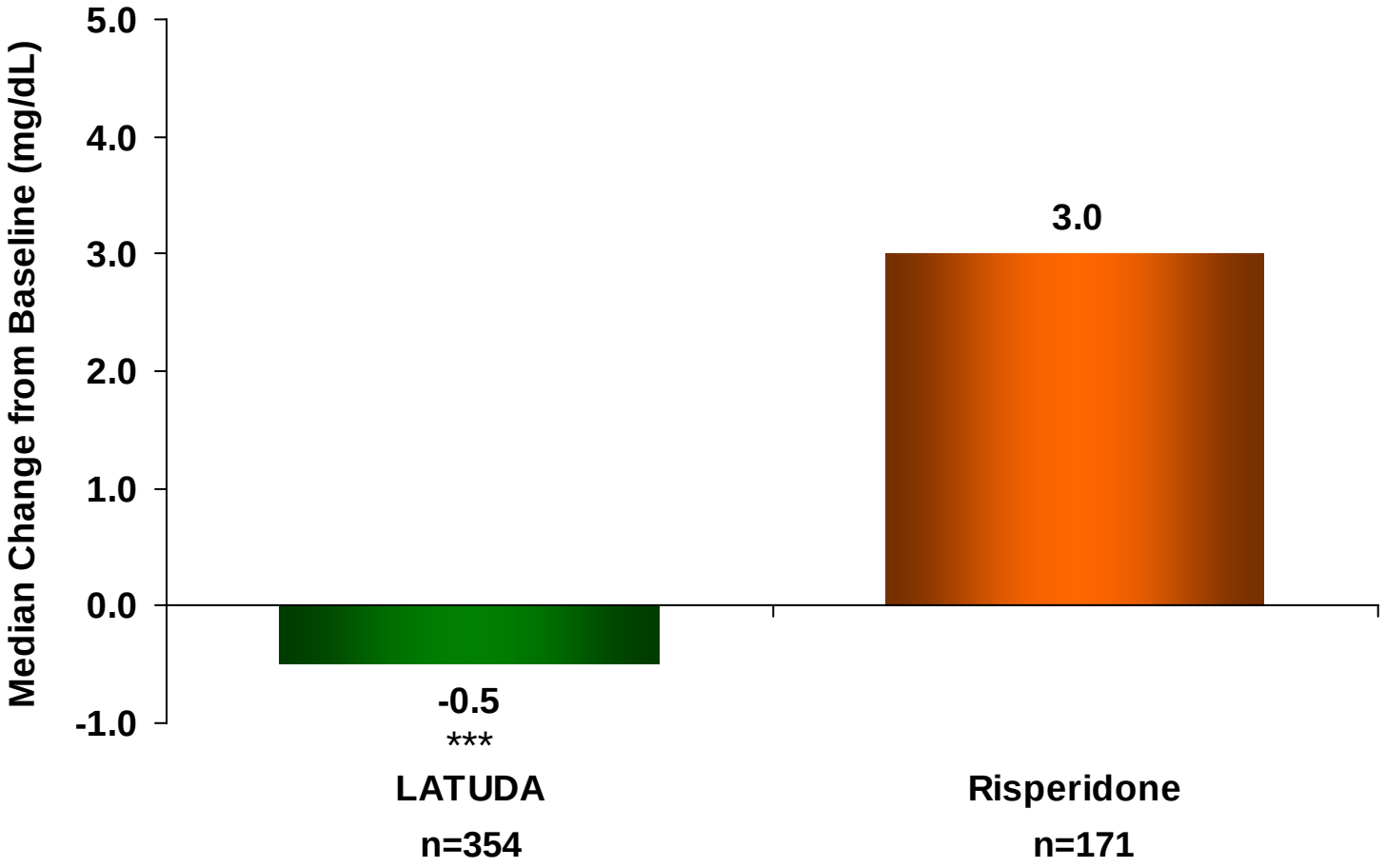
LTSS Safety Results: Triglycerides (LOCF)



DAINIPPON SUMITOMO PHARMA

LTSS Safety Results: Glucose (LOCF)



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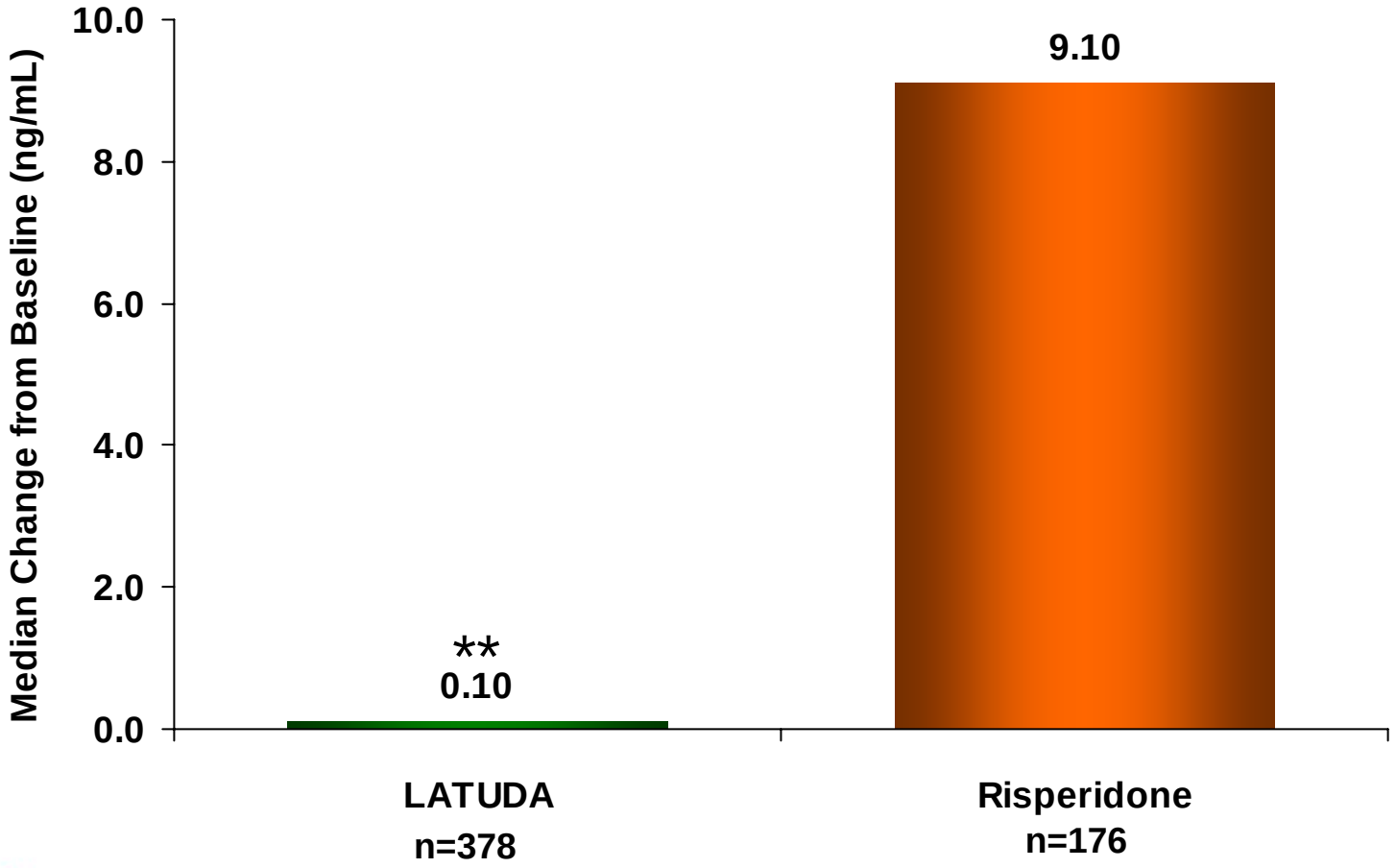
***p= 0.001

LTSS Safety Results: Prolactin (LOCF)



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**p=0.001

LTSS: Selected Common AEs for LATUDA and Risperidone

Adverse Event	LATUDA (n=419)	Risperidone (n=202)
Nausea	16.7 %	10.9 %
Akathisia	14.3	7.9
Vomiting	10.0	3.3
Weight Increased	9.3	19.8
Somnolence	13.6	17.8
Psychotic Disorder	5.0	7.4
Constipation	1.9	6.9
Dystonia	3.1	5.9
Parkinsonism	4.3	5.4

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Long Term Safety Trial Summary

- Discontinuation rate was higher for LATUDA vs. risperidone
  - LATUDA completer rate: 34%
  - Risperidone completer rate: 44%
- Effects on weight and glucose for LATUDA suggest benefits from a metabolic risk perspective
- Minimal elevation in prolactin in LATUDA-treated patients
- Most frequent LATUDA adverse events were nausea, akathisia and vomiting

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Current and Planned LATUDA Studies in Schizophrenia

Study	Timing	Purpose	Post-Marketing
Switch Study in Schizophrenia	Initiated in Q3 2010	Provide info on impact on patients switching from one atypical antipsychotic therapy to LATUDA	
Schizophrenia Maintenance Study	Planned Start Q3 2011	Supports efforts to obtain maintenance claim in label. Requirement for EMA submission	✓
Low-dose Schizophrenia Study with 20 mg/d	Planned Start Q2 2012	Identify lowest therapeutic dose for LATUDA	✓
Pediatric (13-17 yrs) PK Study	Planned Start Q3 2011	Supports potential opportunity for US patent extension	✓
Pediatric (13-17 yrs) Efficacy Study	Planned Start Q2 2012	Supports potential opportunity for US patent extension	✓

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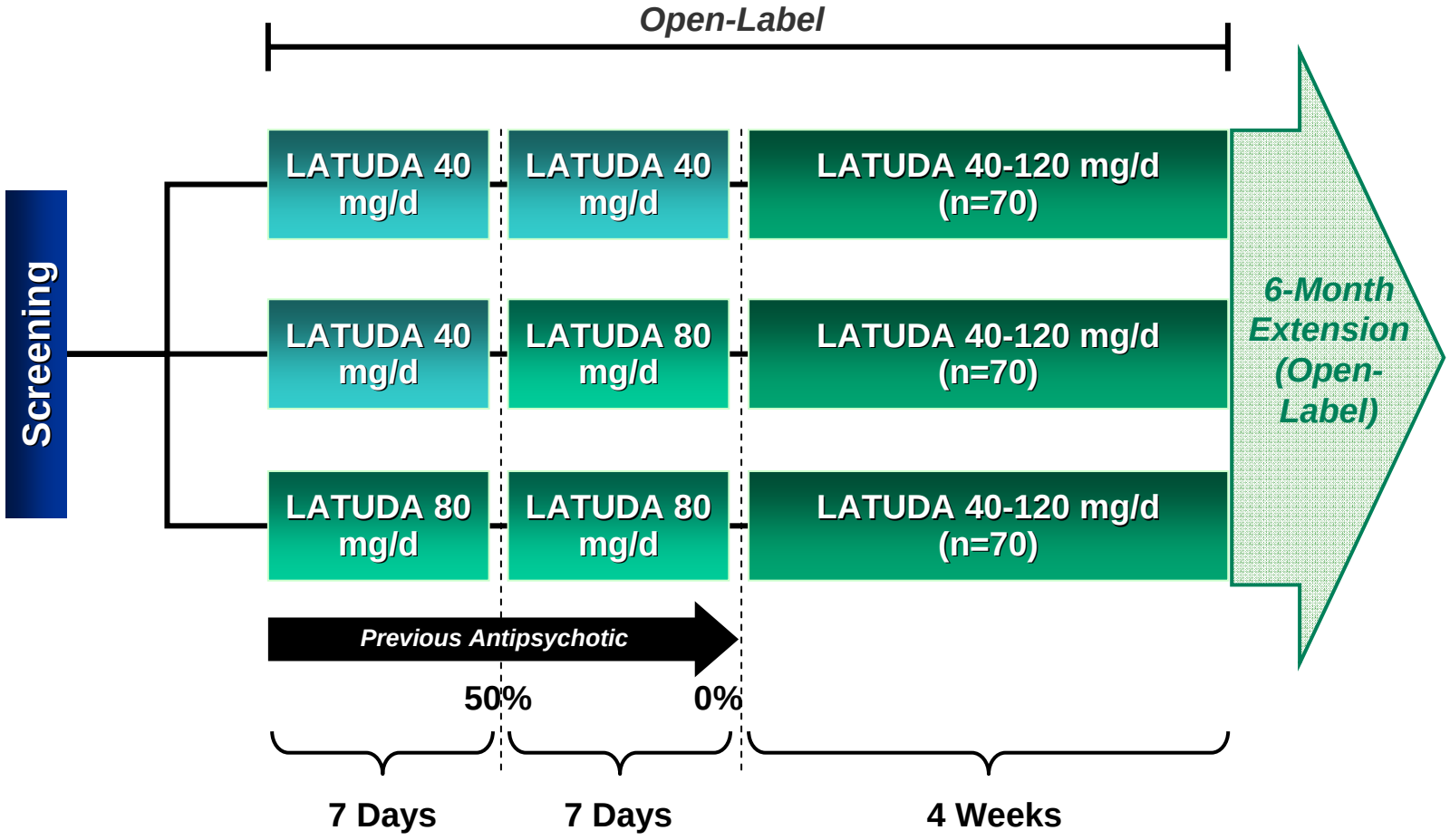
LATUDA Switch (Study 289 and 290) in Schizophrenia



As of January 17, 2011, enrollment Is 60% complete

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US only. Patient enrollment ongoing LPI planned: March 2011

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Bipolar Depression Development Plan: PREVAIL Studies

- PREVAIL: **PR**ogram to **EV**aluate **A**ntidepressant **I**mpact of **LATUDA**
- Ongoing global clinical trials for LATUDA in Bipolar Depression will evaluate effectiveness of LATUDA as
  - Monotherapy
  - Adjunct therapy
  - Maintenance therapy
- Lower, flexible dose range of LATUDA – 20 to 120 mg/day
- Short-term 6 weeks and 24 weeks in an open-label extension
- sNDA planned for 1H/2012

Study Detail	*Timing*
PREVAIL 1 – Add-on therapy added to treatment with lithium or divalproex	Initiated in April 2009 – Estimated completion: Q4 2011
PREVAIL 2 – Monotherapy	Initiated in April 2009 – Estimated completion: Q4 2011
PREVAIL 3 – Add-on therapy added to treatment with lithium or divalproex	Initiated in December 2010
PREVAIL Extension	PREVAIL 1, 2, 3 trial participants to enter into 24 week open-label extension

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LATUDA Global Development Plan

- United States
  - Launch in early February 2011 for Schizophrenia
  - Bipolar depression sNDA planned for 1H/2012
  - Other indications under consideration:
    - Bipolar maintenance: study initiation 3rd Q 2011 (12 months to complete)
    - MDD with mixed features: study initiation 2nd Q 2011 (12 months to complete)
  - IM depot formulation in progress – timelines under development
- Japan
  - Phase 3 data analysis currently underway
- China
  - Expected submitting IND in 2011
- Europe
  - Active partnering discussions in process
- Canada
  - Expected filing at some point in 2011

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The statements made in this presentation material are forward-looking statements based on management's assumptions and beliefs in light of information available up to the day of announcement, and involve both known and unknown risks and uncertainties.

Actual financial results may differ materially from those presented in this document, being dependent on a number of factors.

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