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TREATMENT	:	CONFIDENTIAL
FROM	:	Mitchner, Natasha
TO	:	'Christina Goetjen'; 'Jeff Lawrence'; 'Bill Heydorn'
DATE	=	11/20/2001
TIME	:	03:49:24 PM
SUBJECT	:	Wagner Hot Topics slides
FOLDER	:	Outlook Folders\Personal Folders\ACNP 2001
SOURCE	:	Heydorn, Bill
ATTACHMENT	:	\\bh-app1\ConcordanceData\Production 2012-05-05\EMAILS\Concordance \Attachments\MDL-FOREM0000904\001.Wagner hot topic3.ppt
MESSAGEID	:	<34524CC5F938D411BFAE00508BACFE480785A176 @midwx02bsmg.bsmg.com>
BODY	:	Hello,

Attached please find the final slides submitted to ACNP on behalf of Dr. Wagner. Working with Dr. Wagner and Charley Flicker, we finalized the slides yesterday. If you find additional changes, please let me know and I can see if ACNP has time to make changes. I am also working on the accompanying poster and the manuscript is in the final stages so you should have it later today or tomorrow.

Christina-I just wanted to make sure that you saw the final product since you were involved in the early planning. Have a nice holiday and we look forward to hearing the good news!

Thanks,

Natasha

<<Wagner hot topic3.ppt>>

Citalopram Treatment of Pediatric Depression: Results of a Placebo-Controlled Trial

Karen Dineen Wagner, MD, PhD

Clarence Ross Miller Professor and Vice Chair

Department of Psychiatry and Behavioral Sciences

Director, Division of Child and Adolescent Psychiatry

University of Texas Medical Branch

Galveston, TX

Pediatric Depression

- **Approximately 1% of children and 5% of adolescents suffer from depression (Lewinsohn 1993 and 2000)**
- **Mean duration of depressive episodes is 9 months**
- **Substantial risk of relapse (54%) (McCauley 1993)**
- **Significant impairment in school performance, peer relationships and family functioning**
- **Continuity of pediatric depression into adulthood (Weissman 1999)**
- **Lack of success of pharmacological treatment trials in pediatric depression**

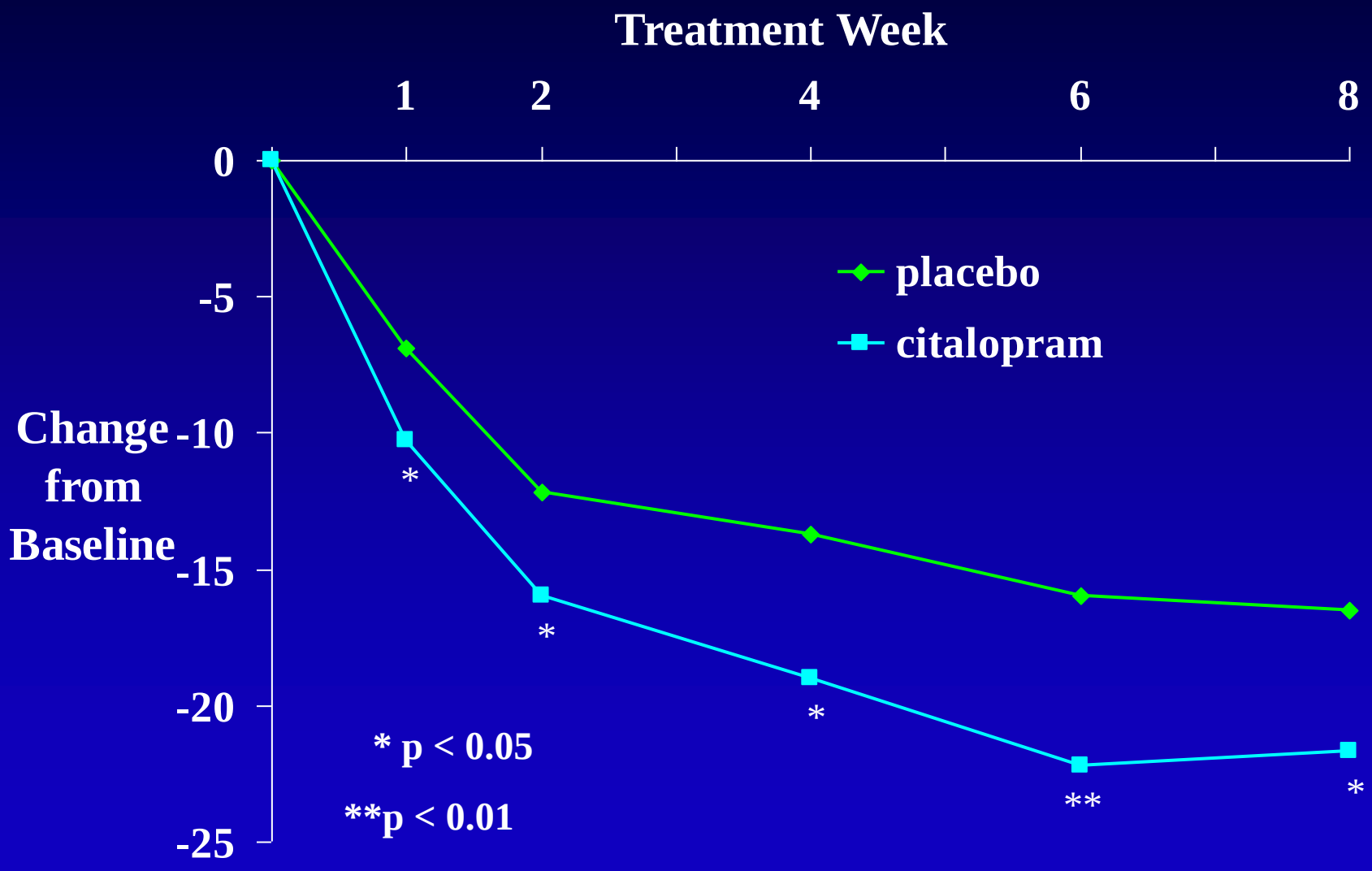
Study Design

- Double-blind, placebo-controlled, flexible dose
- Diagnosis of major depressive disorder
- 174 outpatients, 7-17 years of age
- Two treatment groups
  - Placebo
  - Citalopram 20-40 mg/day
- One-week single-blind placebo lead-in
- Eight weeks double-blind treatment
- Primary efficacy measure: CDRS-R

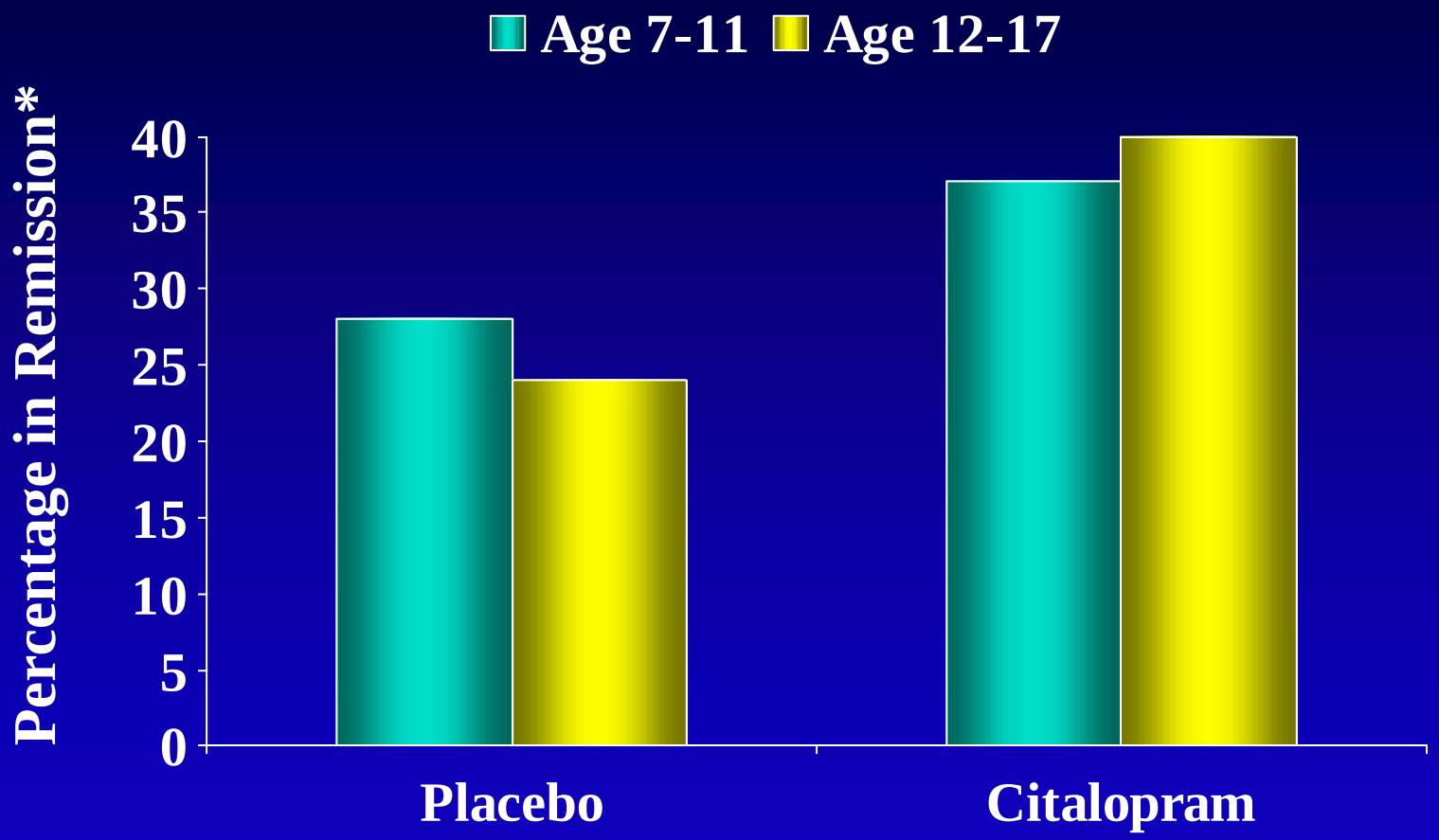
Baseline Characteristics

	Placebo n=85	**Citalopram n=89**
Age (mean years, range)	12.1 (7-17)	12.1 (7-17)
Gender (% female)	54%	53%
Race (% Caucasian)	73%	81%
Duration of illness (years)	2.2	2.3
CDRS-R (mean)	57.8	58.8
CGI-S (mean)	4.3	4.4

CDRS-R


Treatment Week
1
2
4
6
8
0
-5
-10
-15
-20
-25
Change from Baseline
placebo
citalopram
*
*
*
**
*
* p < 0.05
**p < 0.01

Remission Rate by Age Group



*CDRS-R ≤ 28 at study endpoint

Citalopram Dose

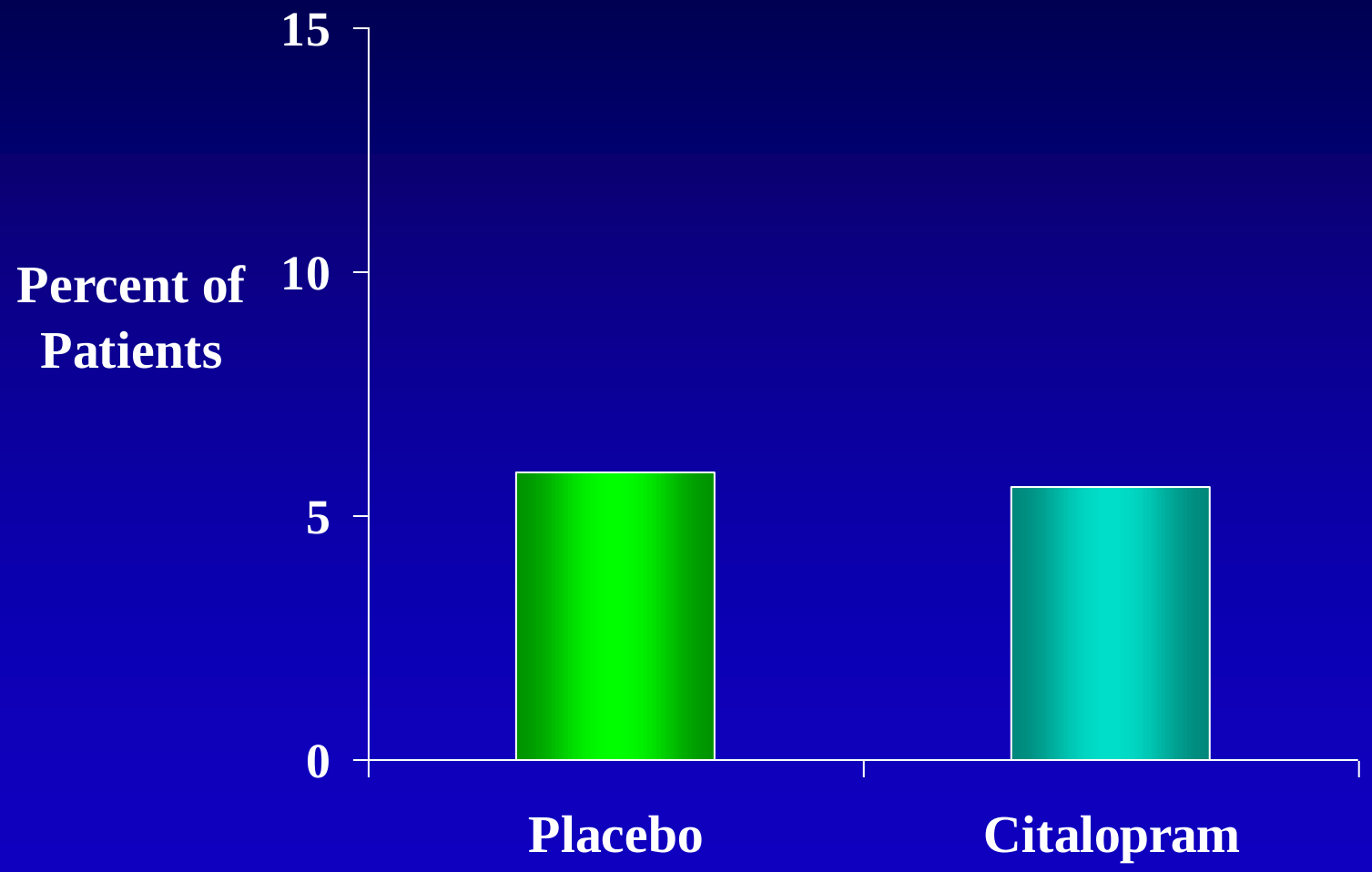
	Children n=45	Adolescents n=47
Mean	23.3 mg/day	24.4 mg/day

Most Frequent Adverse Events

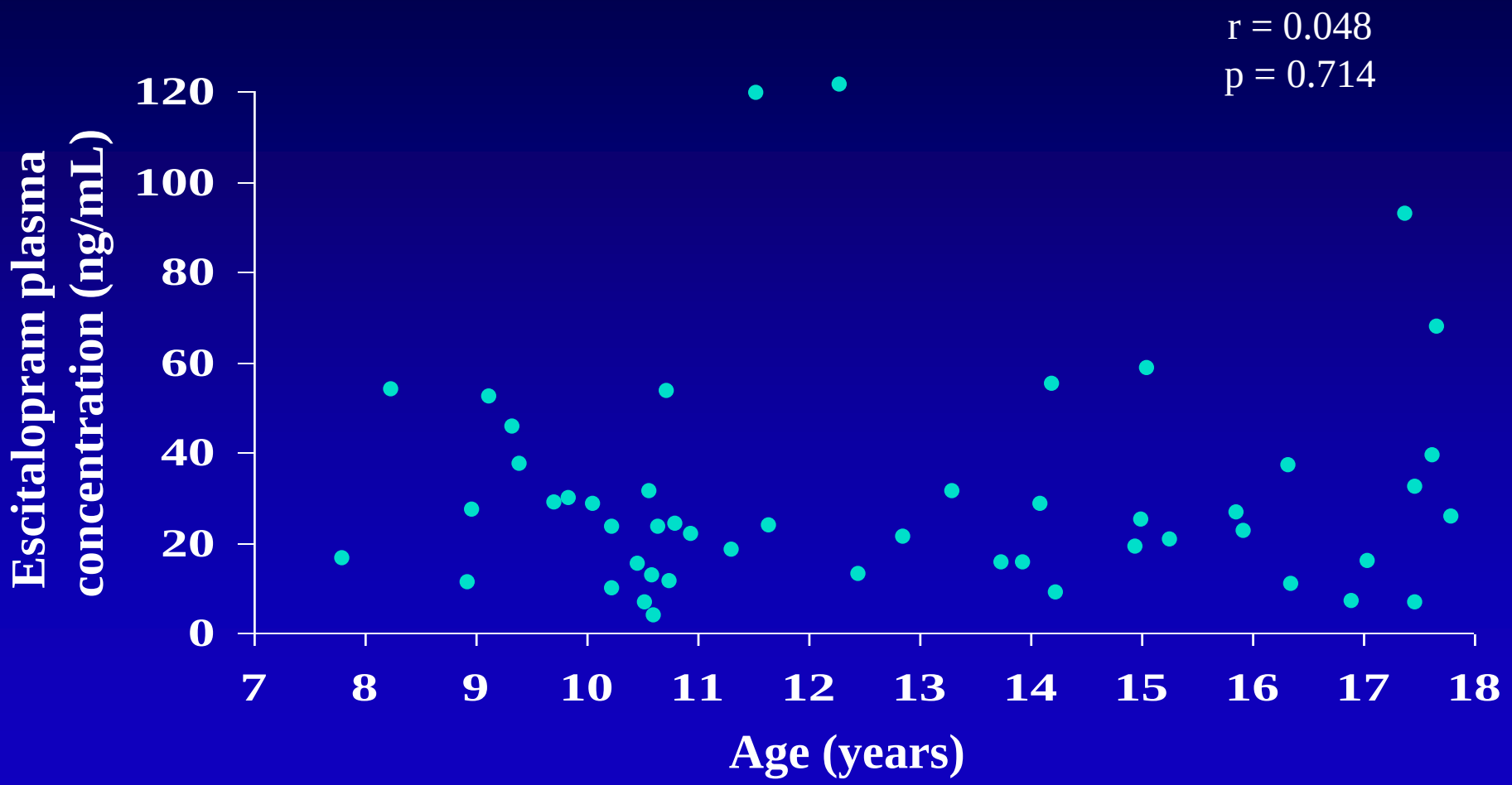
Adverse Event*	Placebo N=85	Citalopram N=89
Headache	20%	19%
Nausea	4%	13%
Rhinitis	6%	13%
Abdominal pain	7%	11%
Influenza-like symptoms	0%	7%

*All adverse events occurring in more than 5 citalopram-treated patients

Discontinuation for Adverse Events



Age vs. Escitalopram Plasma Concentration



Conclusions

- Citalopram treatment significantly improved symptoms of depression, relative to placebo, in both children and adolescents
- Significant therapeutic benefit was observed beginning in the first week of double-blind treatment
- Citalopram tolerability was similar to that of placebo, with a benign side effect profile