



AVANIR[™]
pharmaceuticals

September 2011



NUEDEXTA[™]
(dextromethorphan HBr and
quinidine sulfate) Capsules

Forward-looking Statement

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding Avanir's plans, potential opportunities, financial or other expectations, projections, goals objectives, milestones, strategies, market growth, timelines, legal matters, product pipeline, clinical studies, product development and the potential benefits of its commercialized products and products under development are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including the risks and uncertainties associated with Avanir's operating performance and financial position, the market demand for and acceptance of Avanir's products domestically and internationally, research, development and commercialization of new products domestically and internationally, reliance upon the collaborative efforts of others, competition domestically and internationally, the success of external business-development activities, intellectual property rights, government regulation, obtaining and maintaining regulatory approvals domestically and internationally, government investigations, litigation, including, but not limited to Avanir's ability to protect its patents and other intellectual property both domestically and internationally, the occurrence of adverse safety events delay or failure to gain acceptance by the medical field domestically and internationally, dependence on third parties for supply, manufacturing and distribution, delay or failure to adequately build or maintain the necessary sales, marketing, supply chain management and reimbursement capabilities on our own or enter into arrangements with third parties to perform these functions in a timely manner or on acceptable terms, and other risks detailed from time to time in the Company's most recent Annual Report on Form 10-K and other documents subsequently filed with or furnished to the Securities and Exchange Commission. These forward-looking statements are based on current information that may change and you are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update any forward-looking statement to reflect events or circumstances after the issuance of this press release.

Avanir Investment Highlights

Avanir is a specialty biopharmaceutical company focused on CNS therapeutics



NUEDEXTA in Pseudobulbar Affect (PBA)

- *First and only FDA approved therapy for PBA*
- *Large, underserved market*
- *High unmet medical need*



NUEDEXTA/AVP-923 potential follow-on indications

- *MS-related pain*
- *Emotional lability associated with dementia*
- *Diabetic peripheral neuropathic pain*



Corporate

- *Strong balance sheet*
- *Global Rights to NUEDEXTA*

Calendar Year 2011 Milestones

- ✓ Launched NUEDEXTA in PBA
- ✓ Filed IND for AVP-923 follow-on indication (MS-related pain)
- ✓ Launched PRISM PBA Patient Registry
- ✓ Obtained regulatory clarity from the European Medicines Agency (EMA)
- ✓ Received a pediatric waiver from the EMA for NUEDEXTA
- ✓ Achieved record prescriptions in July (2,746) and August (3,556)
- ◆ Enroll first patient for AVP-923 in MS-related pain (PRIME Study)
- ◆ Prepare to file NUEDEXTA PBA application with EMA

PBA Market Overview



NUEDEXTA™
(dextromethorphan HBr and
quinidine sulfate) Capsules

PBA Clinical Summary

- ◆ Neurologic disorder causing involuntary emotional outbursts
 - Crying and or laughing episodes
 - Incongruent or exaggerated to patient's inner mood
 - Usually occur several times per day
 - Episodes last from seconds to minutes
- ◆ Episodes can be severe and cause significant impairment
- ◆ Occurs secondary to underlying neurologic diseases or injuries
 - Alzheimer's disease, amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), Parkinson's disease, stroke, traumatic brain injury
 - Pathophysiology of PBA is widely believed to involve injury to the neurologic pathways that regulate affect



PBA and Functional Impairment...

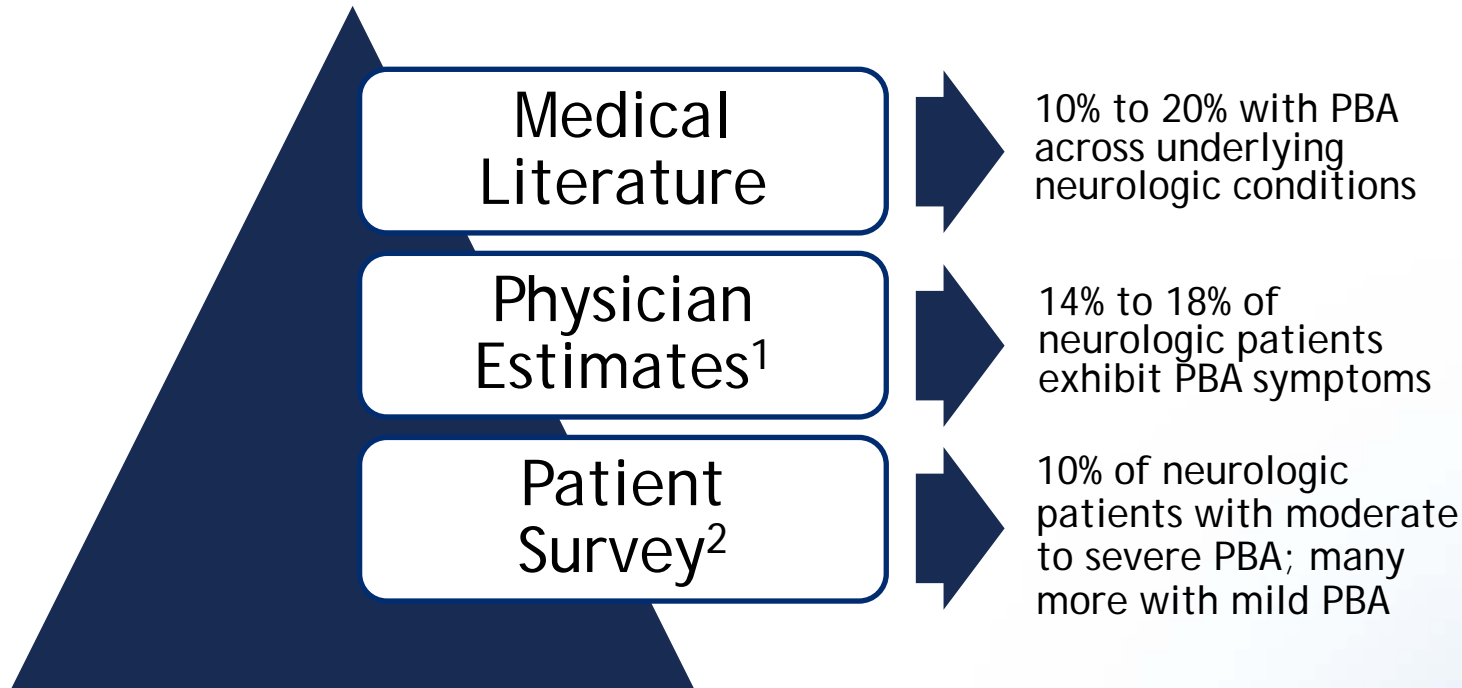
- ◆ The clinical presentation of PBA has been described for over a century...more recent observations include:
 - Impaired social and occupational function¹⁻³
 - Embarrassment, social phobia, withdrawal, and isolation^{1,4}
 - Inability to participate in rehabilitative therapy⁵

43% of patients say PBA contributed to becoming housebound⁶

1. Dark FL, et al. *Aust N Z J Psychiatry*. 1996;30(4):472-479. 2. Arciniegas DB, Topkoff J. *Semin Clin Neuropsychiatry*. 2000;5(4):290-306. 3. Shaibani AT, et al. *Neuropsychiatry Neuropsychol Behav Neurol*. 1994;7(4):243-250. 4. Robinson RG, et al. *Am J Psychiatry*. 1993;150(2):286-293. 5. Zeilig G, et al. *Brain Injury*. 1996;10(8):591-597. 6. Avanir data on file

PBA Prevalence

18 to 20 million in U.S. with underlying neurologic conditions



- ◆ Estimated 5.1 million with mild PBA (~28%)
- ◆ Estimated 1.8 million with moderate-to-severe PBA (~10%)

¹ Physician market research - Avanir data on file

² Work S, et al. *Adv Ther.* 2011; DOI 10.1007/s12325-011-0031-3

NUEDEXTA Overview

First and only FDA approved therapy for PBA

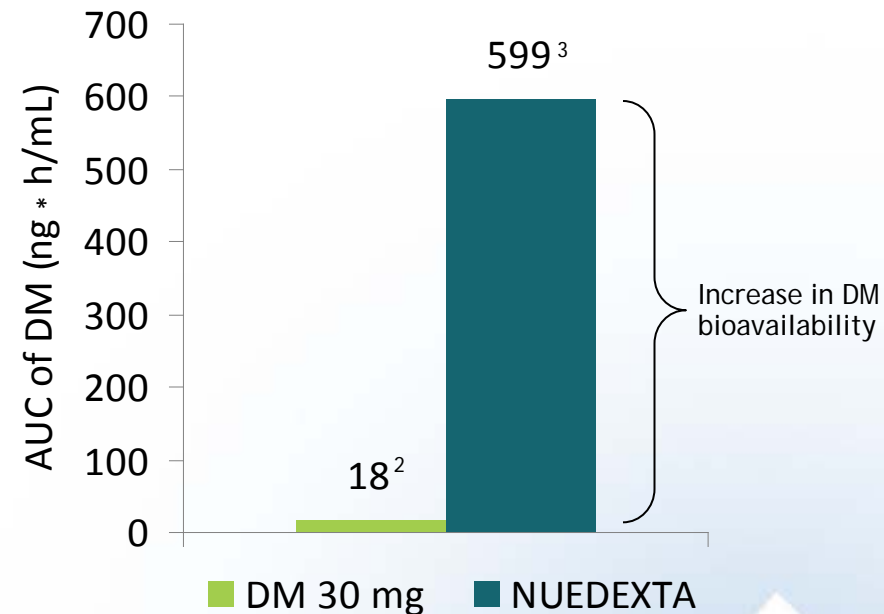


NUEDEXTA[™]
(dextromethorphan HBr and
quinidine sulfate) Capsules

NUEDEXTA Pharmacology

- ◆ Dextromethorphan hydrobromide (20 mg)
 - The ingredient active in the central nervous system¹
- ◆ Quinidine sulfate (10 mg)
 - A metabolic inhibitor enabling therapeutic dextromethorphan concentration¹

Pharmacokinetics of DM



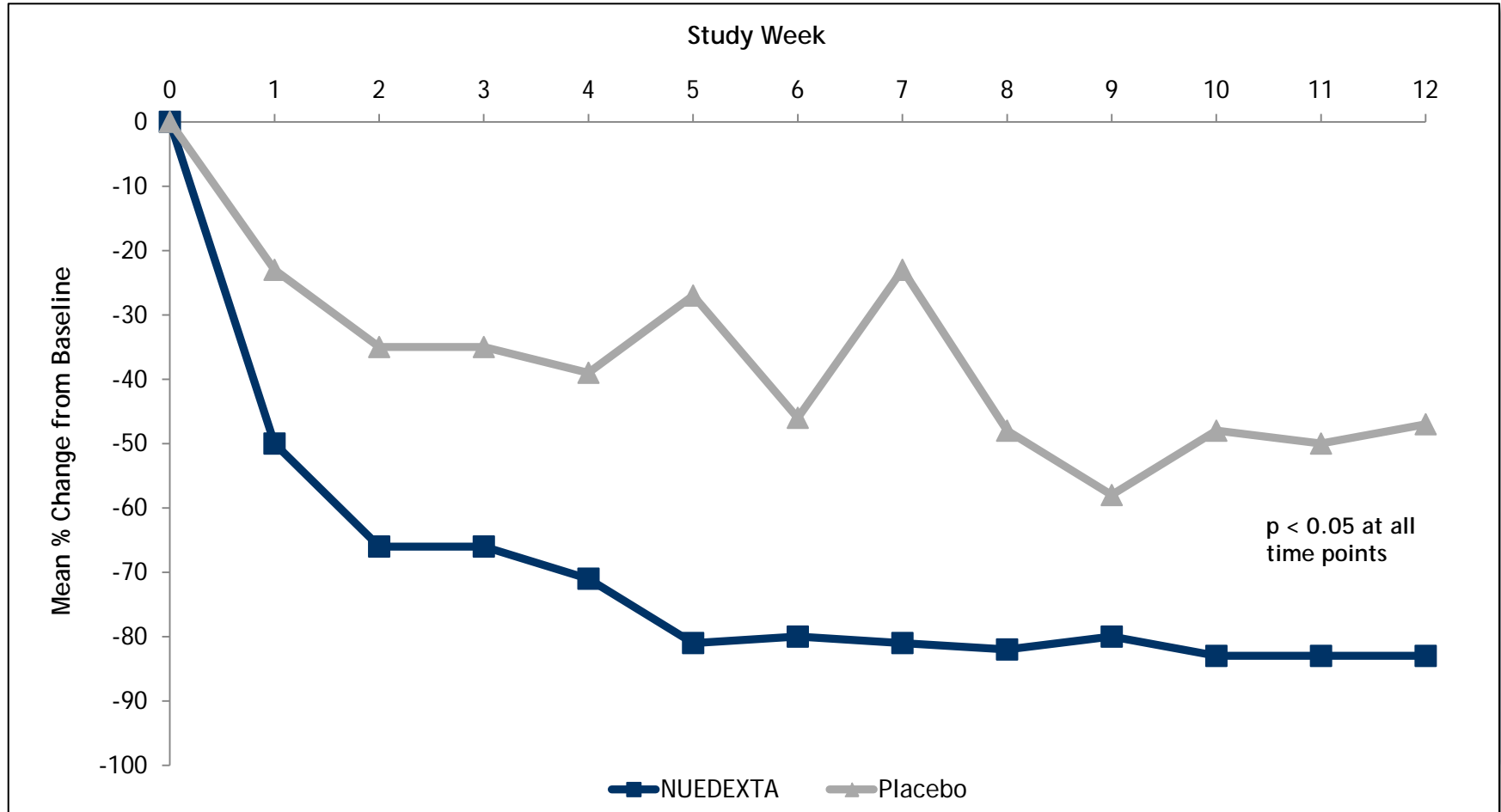
1. NUEDEXTA (dextromethorphan HBr and quinidine sulfate) capsules [prescribing information]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc; 2010. 2. Pope LE, et al. *J Clin Pharmacol.* 2004;44(10):1132-1142.

AUC, area under the time concentration curve; DM, dextromethorphan.

2. Pope LE, et al. *J Clin Pharmacol.* 2004;44(10):1132-1142.

3. Data on file: STAR Trial. Avanir Pharmaceuticals, Inc, Aliso Viejo, CA; 2009.

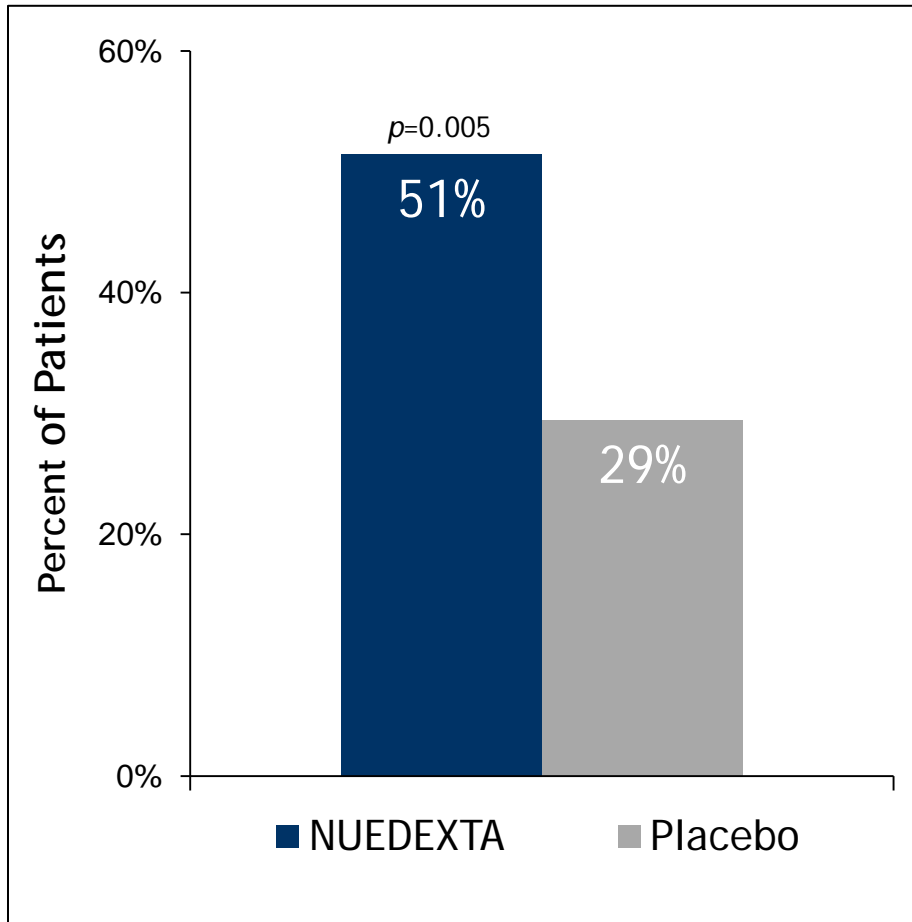
Mean Weekly PBA Episode Decrease



- ◆ Over 80% reduction in mean weekly episodes from baseline to end of study
 - 50% reduction in mean episodes during the first week

PBA Remission

Percent of Patients with Remission*



Significant Efficacy

- ◆ 51% of patients taking NueDexta achieved PBA episode remission*
- ◆ Significant reduction in CNS-Lability Scale score vs. placebo

* Remission (ITT population) was defined as no episodes during the last 14 days of the study (EOS)
Adapted from Pioro EP, Ann Neurol. 2010;68(5):693-702.

NUEDEXTA Commercialization



NUEDEXTA™
(dextromethorphan HBr and
quinidine sulfate) Capsules

NUEDEXTA Commercialization Strategies

Increase diagnosis and treatment of PBA

Drive rapid trial and adoption of NUEDEXTA

Minimize payer and distribution barriers

Increase Diagnosis and Treatment of PBA

Programs and Tactics

◆ Patient Advocacy Group initiatives

- Advocacy Summit
- PBA surveys (stroke, TBI, MS)
- PBA educational events (webinars)



◆ PBAinfo.org

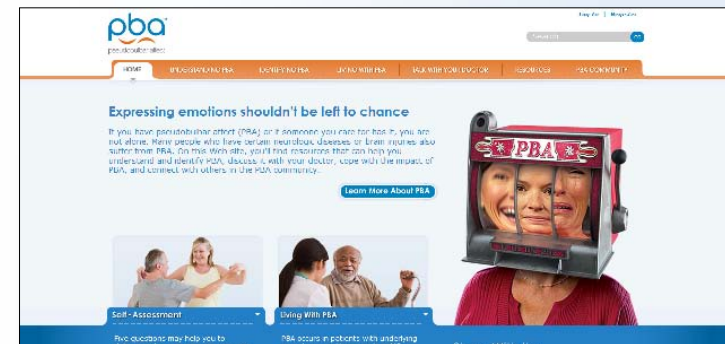


◆ Online and print advertising



◆ Patient education materials

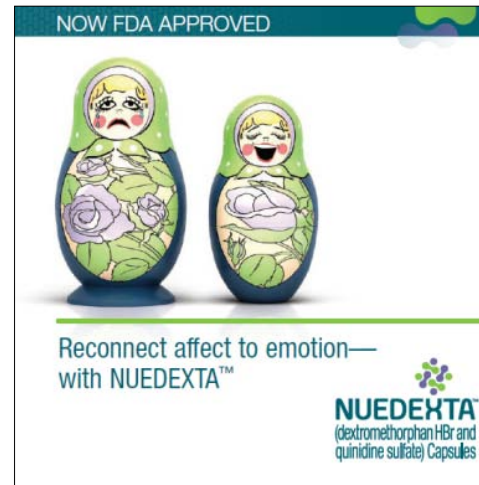
- PBA Patient brochure
- PBA fact sheet
- PBA discussion guide
- PBA tool kit for self help groups



Drive Rapid Trial and Adoption of NUEDEXTA

Programs and Tactics

- ◆ Dedicated specialty sales force
- ◆ Targeted physicians
 - Neurology
 - Psychiatry
 - Internal Medicine
- ◆ NUEDEXTA Sales Aid
- ◆ NUEDEXTA Product Samples
- ◆ Physician Speakers Bureau
- ◆ Medical Conference Activities
- ◆ NUEDEXTA.com & Call Center



Minimize Payer and Distribution Barriers Programs and Tactics

- ◆ Co-Pay assistance program
- ◆ Reimbursement counseling
- ◆ AMCP dossier
- ◆ Pharmacy sell sheets
- ◆ Trade materials
- ◆ MCO Contracting

Free Sample Offer

Receive 13 Free Capsules of NUEDEXTA

Limit One Free Sample voucher per patient. Redeem for product only when accompanied with a valid, signed prescription for NUEDEXTA capsules. Retail claim to McKesson Corporation using RXBIN 610524. For pharmacy processing questions, please call the Help Desk at 1-800-887-7815.

RxBIN: 610524 RxPCN: 1016 RxGRP: 40020184
ISSUER: (80840) ID: XXXXXXXXX

Visit www.mckesson.com for terms and conditions of voucher. Claim shall not be submitted to any public or private third party payer or any federal or state health care program for reimbursement. Submit claim to McKesson Corporation. Offer not valid if repurchased or substituted in any other way. It is illegal for any person to sell, purchase or trade, or offer to sell, purchase or trade, or to counterfeit, this voucher. Prescriber ID# required on prescription. McKesson retains the right to review all records and documentation relating to the fulfillment of this offer.

- This offer is valid for U.S. residents only.
- Dispense this product at no cost or co-pay to the patient.
- No purchase required. Use of this offer does not create any obligation or involve any past or future purchase requirement.
- By using or processing this voucher you understand and agree to comply with these offer terms.

This offer may be terminated, rescinded, revoked or amended by Avanis Pharmaceuticals, Inc. at any time, without notice.

Please see Important Safety Information about taking NUEDEXTA and full prescribing information at www.NUEDEXTA.com.

NUEDEXTA
dextromethorphan HBr and
quinidine sulfate Capsules

20mg/10mg

AVANIS
Pharmaceuticals, Inc.
www.Http://www.AVANIS.com

AMCP Dossier for

NUEDEXTA

(dextromethorphan HBr and
quinidine sulfate) Capsules

AVANIS
Pharmaceuticals, Inc.
www.Http://www.AVANIS.com

Introducing NUEDEXTA™—the first and only FDA-approved treatment for PBA*

Prescribing Information Summary

How supplied	13x10 capsules
Controlled substance	Class II (Schedule II)
Strength	20mg/10mg capsules
Package configurations	13x10 capsules
NDC number	40020184
SNAC	2499

Clinically significant relief**

NUEDEXTA is indicated for the treatment of moderate-to-severe PBA. PBA is a common side effect of other first-line PBA treatments, and is characterized by a combination of symptoms including: aches and pains, muscle stiffness, and joint pain. PBA is a common side effect of other first-line PBA treatments, and is characterized by a combination of symptoms including: aches and pains, muscle stiffness, and joint pain.

Studies to support the effectiveness of NUEDEXTA were performed in patients with moderate-to-severe PBA. In a randomized, double-blind, placebo-controlled study, NUEDEXTA was not found to be significantly more effective than placebo in the treatment of PBA. However, patients who received NUEDEXTA reported a higher percentage of patients who were able to continue their daily activities and maintain their normal diet.

USAL DISCLAIMER:
NUEDEXTA is a prescription, patient-oriented, fast-acting formulation containing 20mg of dextromethorphan hydrobromide USP, 10mg of quinidine sulfate USP, and certain inactive ingredients in capsules for oral administration. NUEDEXTA is the only FDA-approved treatment for moderate-to-severe PBA. The components of NUEDEXTA have not individually demonstrated efficacy in clinical trials in patients with PBA, and are not FDA-approved for the treatment of PBA. Avanis Pharmaceuticals does not recommend that the individual components of dextromethorphan hydrobromide and quinidine sulfate be prescribed separately or concomitantly for the treatment of PBA.

Call your wholesaler to order NUEDEXTA today!

For customer service and order inquiries, please call 1-800-887-7815. For any other product inquiries, please call 1-800-887-7815. **Please see attached Important Safety Information and full Prescribing Information.**

NUEDEXTA
dextromethorphan HBr and
quinidine sulfate Capsules

20mg/10mg

AVANIS
Pharmaceuticals, Inc.

Pay no More Than \$30*

For your next 6 NUEDEXTA prescriptions. Restrictions apply. (see reverse)

RxBIN: 610524
RxPCN: Loyalty
RxGRP: 50776185
ISSUER: (80840)

ID: XXXXXXXXX

Powered By:

MEKESON
Empowering Healthcare

NUEDEXTA
(dextromethorphan HBr and
quinidine sulfate) Capsules

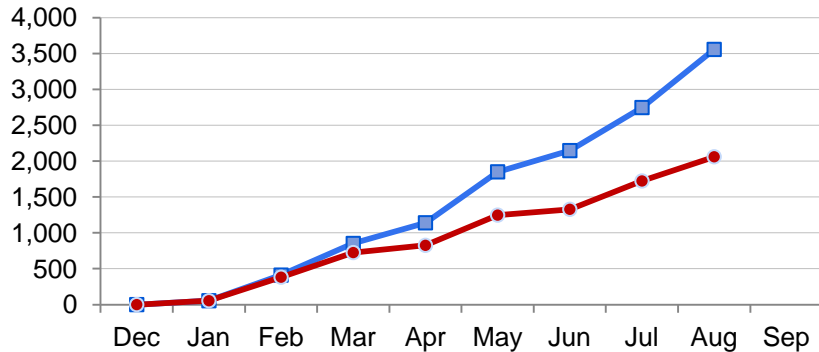
20mg/10mg

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Pharmaceuticals, Inc.

*Maximum benefit of \$40 per prescription regardless of the co-pay amount. Offer restrictions apply.

Launch Metrics

Monthly Prescription Growth



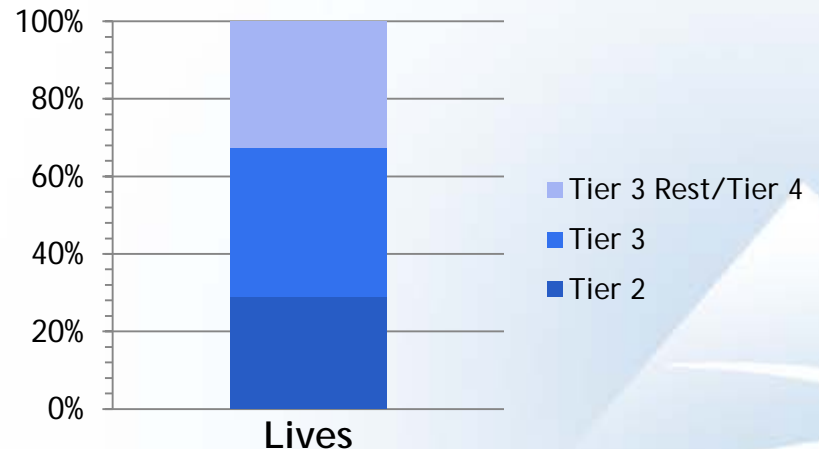
Speakers Bureau**

- ◆ Over 200 physicians trained
- ◆ Over 1300 completed programs
- ◆ Another 190 programs scheduled
- ◆ More than 5,000 attendees

Payer Activity

- ◆ Contract negotiations ongoing
- ◆ Formulary review cycle on schedule
- ◆ Active co-pay assistance program

Payer Coverage (%)*

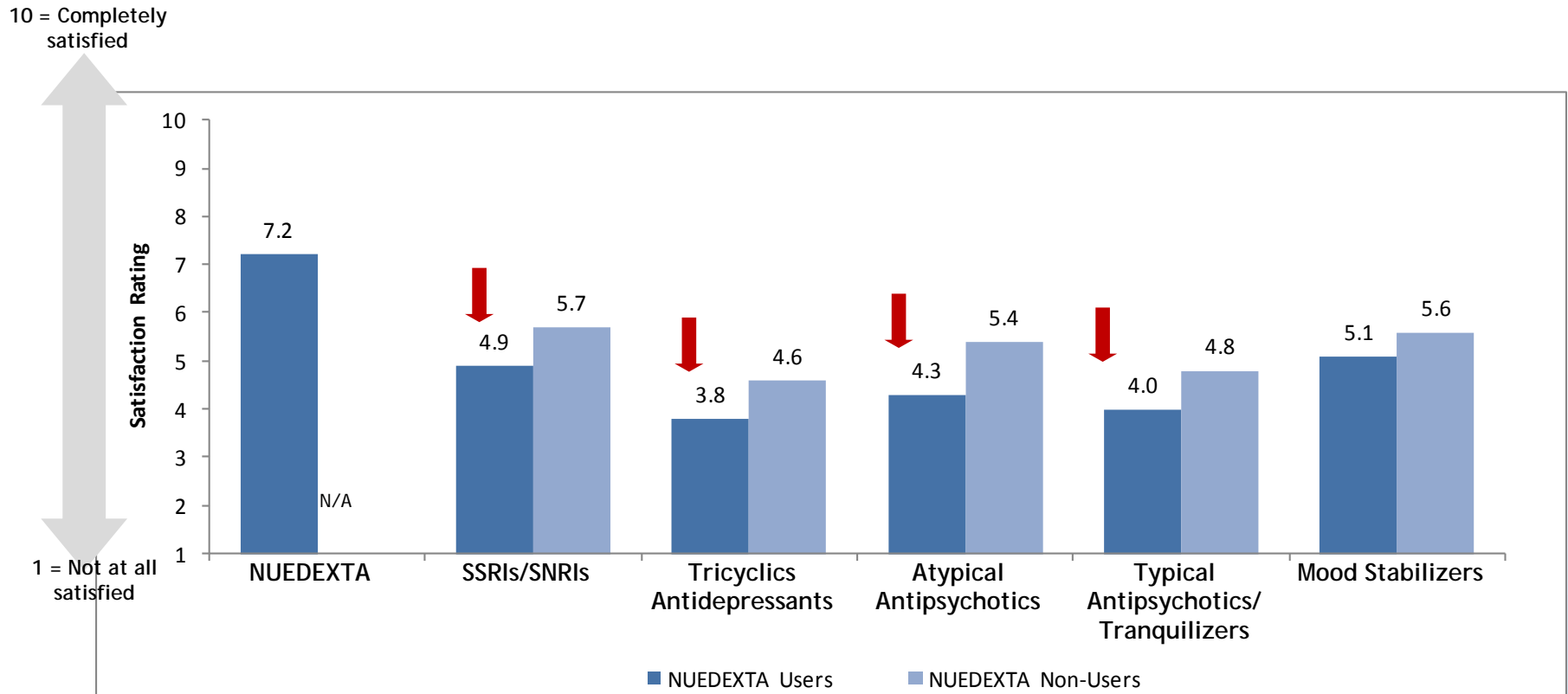


*Reported as of 8/15/11

** Reported as of 9/13/11

PBA Treatment Satisfaction

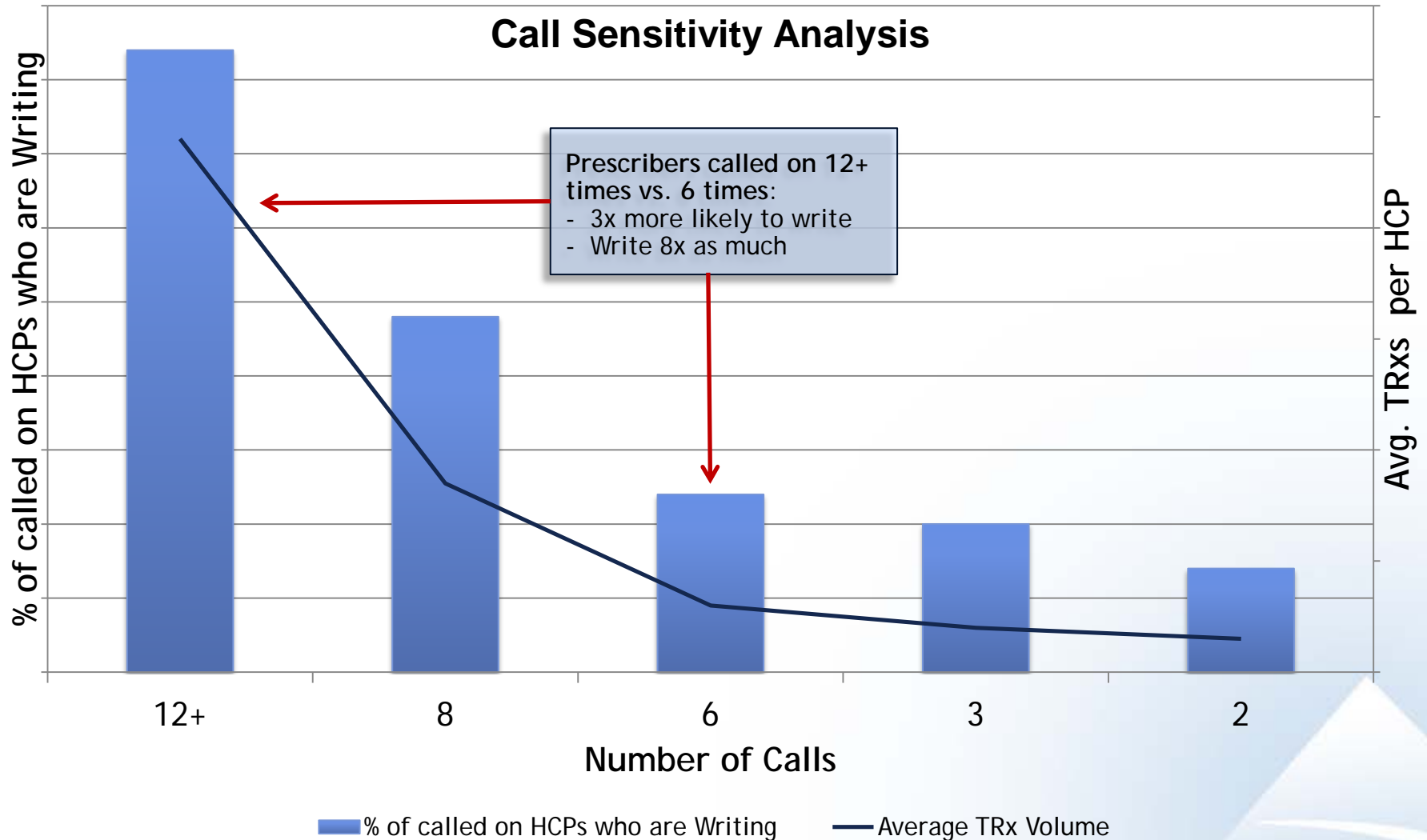
Average Satisfaction Rating for the Following Agents When Used to Treat PBA



↑↓ Significantly greater than/less than NUEDEXTA Non-Users

Base: Have PBA Patients- NUEDEXTA Users (n=43), NUEDEXTA Non-Users (n=172)
[Q10a] Thinking of their use as treatments for PBA, please rate your satisfaction with each of the agents you use.
Physician market research, June 2011 - Avanir data on file

NUEDEXTA is Promotionally Sensitive



AVP-923 Follow-on Indications



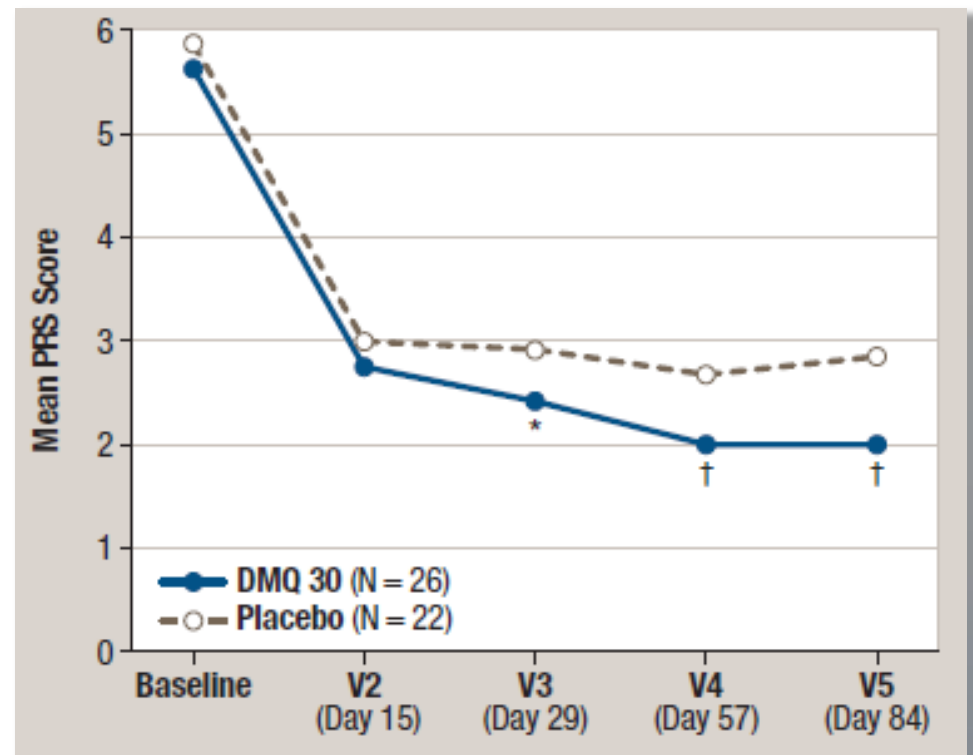
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MS Related Pain: DMQ 30/10mg Dose

Rationale for MS Pain Program

- ◆ Approximately 30% of MS patients suffer central neuropathic pain¹
- ◆ No currently FDA approved therapies
- ◆ Strategically aligned with PBA commercial organization
- ◆ Proof of concept data from two clinical trials

Pain Rating Scale Scores Across Time (MS Patients With Baseline Score ≥ 4)²



* $P = 0.010$, † $P < 0.0001$ t-test for DMQ 30/10 mean versus placebo.

DMQ 20/10 mg did not show a statistically significant P -value versus placebo.

Note: DMQ 30/10mg has not been proven to be safe or effective in the treatment of MS related pain

1. Österberg A, Boivie J, Thuomas KA. Central pain in multiple sclerosis--prevalence and clinical characteristics. Eur J Pain. 2005 Oct; 9(5):531-42. 2. Poster A11, Presented at the 3rd World Congress on Controversies in Neurology (CONy) • Prague, Czech Republic • October, 2009; Secondary endpoint for MS sub-population in Phase III STAR trial; post-hoc efficacy analysis

Study AVR-130 (PRIME): Phase II Trial of AVP-923

Treatment of Central Neuropathic Pain in Patients with MS

Primary Endpoint

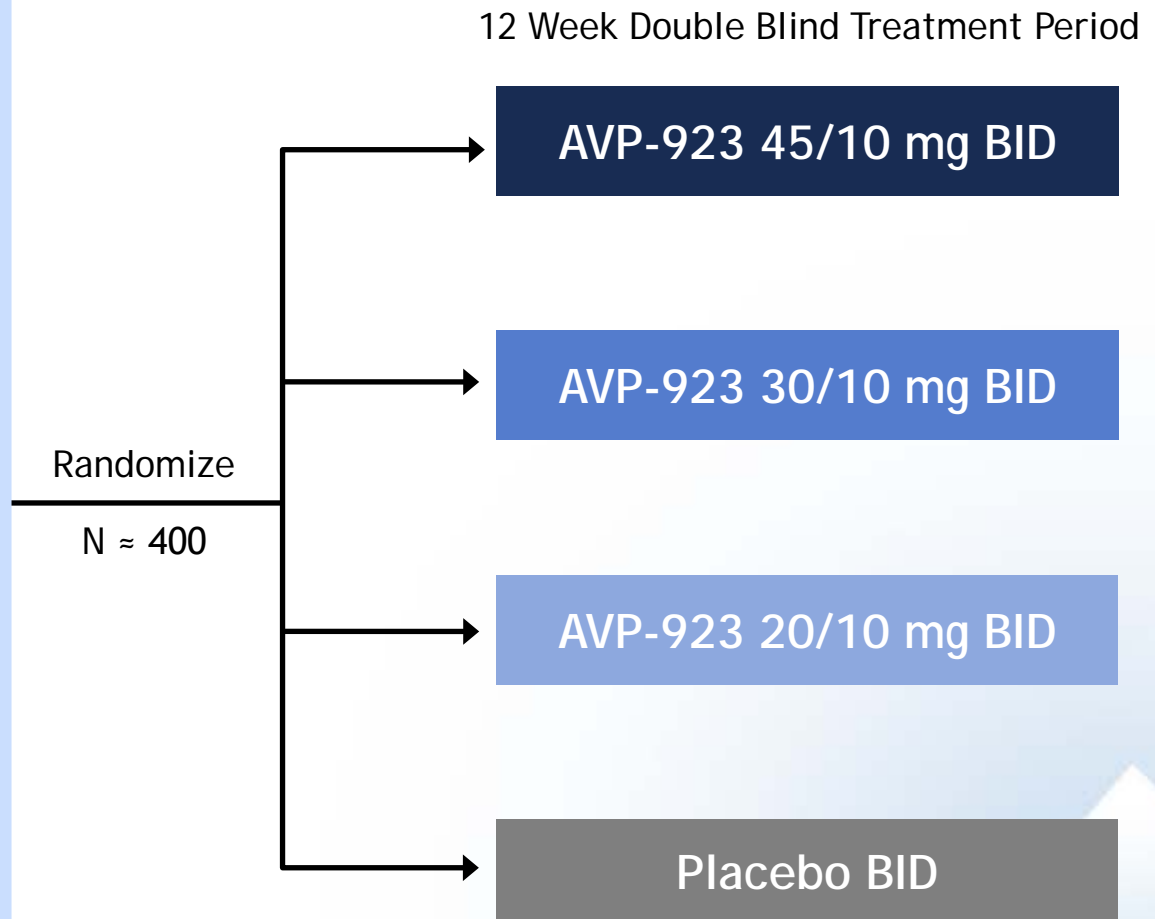
- ◆ Pain Rating Scale

Secondary Endpoints

- ◆ Fatigue Severity Scale
- ◆ Expanded Disability Status Scale
- ◆ MS Impact Scale
- ◆ Pittsburgh Sleep Quality Index
- ◆ MS Neuropsychological Screening Questionnaire
- ◆ Beck Depression Inventory

Additional Information

- ◆ ~ 65 sites



Financials



NUEDEXTA™
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quinidine sulfate) Capsules

Avanir Financial Summary

Balance Sheet

Cash, cash equivalents & marketable securities as of June 30, 2011	\$93.5 million
Debt	No debt

Income Statement

Target Operating Expenses for fiscal 2011	\$67-72 million
Excludes share-based compensation expenses	

* Avanir fiscal year is from October 1 through September 30

Calendar Year 2011 Milestones

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- ◆ Prepare to file NUEDEXTA PBA application with EMA



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www.pbainfo.org



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Important Safety Information About NUEDEXTA

About NUEDEXTA

- ◆ NUEDEXTA® is the first and only FDA-approved treatment for pseudobulbar affect (PBA). NUEDEXTA is an innovative combination of two well-characterized components; dextromethorphan hydrobromide (20 mg), the ingredient active in the central nervous system, and quinidine sulfate (10 mg), a metabolic inhibitor enabling therapeutic dextromethorphan concentrations. NUEDEXTA acts on sigma-1 and NMDA receptors in the brain, although the mechanism by which NUEDEXTA exerts therapeutic effects in patients with PBA is unknown.
- ◆ NUEDEXTA is indicated for the treatment of pseudobulbar affect (PBA). PBA occurs secondary to a variety of otherwise unrelated neurological conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the patient's underlying emotional state. Studies to support the effectiveness of NUEDEXTA were performed in patients with amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS). NUEDEXTA has not been shown to be safe and effective in other types of emotional lability that can commonly occur, for example, in Alzheimer's disease and other dementias. The primary outcome measure, laughing and crying episodes, was significantly lower in the NUEDEXTA arm compared to placebo. The secondary outcome measure, the Center for Neurologic Studies Lability Scale (CNS-LS), demonstrated a significantly greater mean decrease in CNS-LS score from baseline for the NUEDEXTA arm compared to placebo.

Important Safety Information - Continued

NUEDEXTA Important Safety Information

- ◆ NUEDEXTA can interact with other medications causing significant changes in blood levels of those medications and/or NUEDEXTA. NUEDEXTA is contraindicated in patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine and pimozide) and should not be used concomitantly with other drugs containing quinidine, quinine, or mefloquine. NUEDEXTA is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs within the preceding 14 days. NUEDEXTA is contraindicated in patients with a known hypersensitivity to its components.
- ◆ NUEDEXTA may cause serious side effects, including possible changes in heart rhythm. NUEDEXTA is contraindicated in patients with a prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, in patients with heart failure as well as patients with, or at risk of, complete atrioventricular (AV) block, unless the patient has an implanted pacemaker.
- ◆ NUEDEXTA causes dose-dependent QTc prolongation. When initiating NUEDEXTA in patients at risk of QT prolongation and torsades de pointes, electrocardiographic (ECG) evaluation of QT interval should be conducted at baseline and 3-4 hours after the first dose.
- ◆ The most common adverse reactions in patients taking NUEDEXTA are diarrhea, dizziness, cough, vomiting, weakness, swelling of feet and ankles, urinary tract infection, flu, elevated liver enzymes, and flatulence.
- ◆ NUEDEXTA may cause dizziness. Precautions to reduce the risk of falls should be taken, particularly for patients with motor impairment affecting gait or a history of falls.
- ◆ Patients should take NUEDEXTA exactly as prescribed. Patients should not take more than 2 capsules in a 24-hour period, make sure that there is an approximate 12-hour interval between doses, and not take a double dose after they miss a dose.
- ◆ These are not all the risks from use of NUEDEXTA. For additional important safety information about NUEDEXTA, please see the full Prescribing Information at www.NUEDEXTA.com.