

Acorda Acquisition of Civitas Therapeutics

September 24, 2014



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Civitas Acquisition Overview

- \$525 million cash transaction
- Worldwide rights to CVT-301
 - Phase 3-ready for OFF episodes in Parkinson's disease
 - Significant commercial opportunity
- ARCUS™ pulmonary delivery technology
- GMP manufacturing facility based in Chelsea, MA

Strategic Rationale

- Late stage asset with significant unmet medical need
- Compelling Phase 2b data; Phase 3 study expected to initiate in early 2015
- Leverages Acorda's neurological expertise, and commercial organization
- Worldwide rights provide opportunity to establish a global footprint



CVT-301

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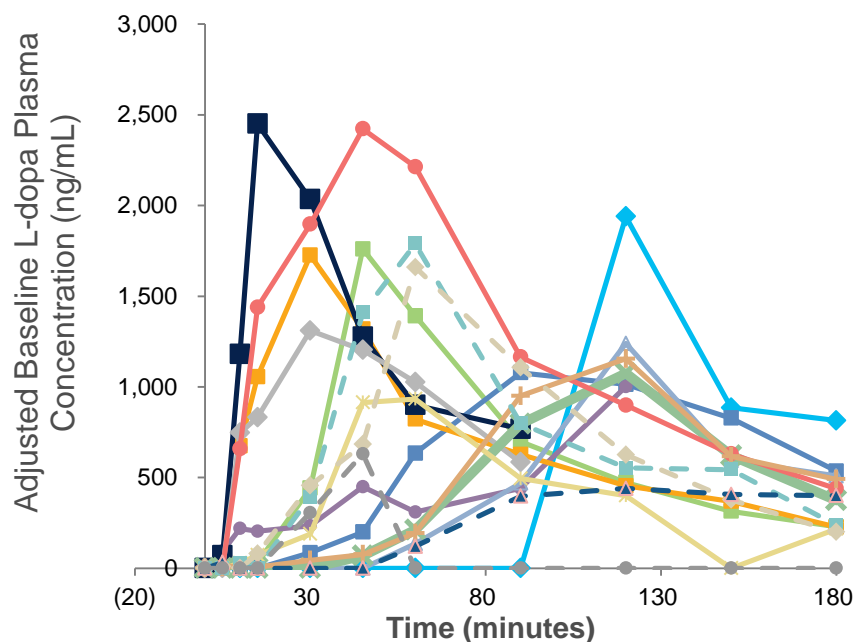
Parkinson's Disease – OFF Episodes

- More than 1 million people in the U.S. suffer from Parkinson's disease
- >70% of patients treated with oral L-dopa
 - Of these, 50% will go on to develop OFF episodes within 5 years of L-dopa use
 - OFF episode symptoms include slow movement, muscle rigidity and tremor at rest
- Significant need for reliable treatment of OFF episodes

Improving the Standard of Care Possible

Current Oral Standard of Care

Data from Phase 2a in fasted PD patients



BARRIERS TO GETTING ORAL L-DOPA TO THE CNS

L-dopa structure and oral route related challenges

- Reduced active transport and food effect
- Reduced available dopamine due to metabolic pathways

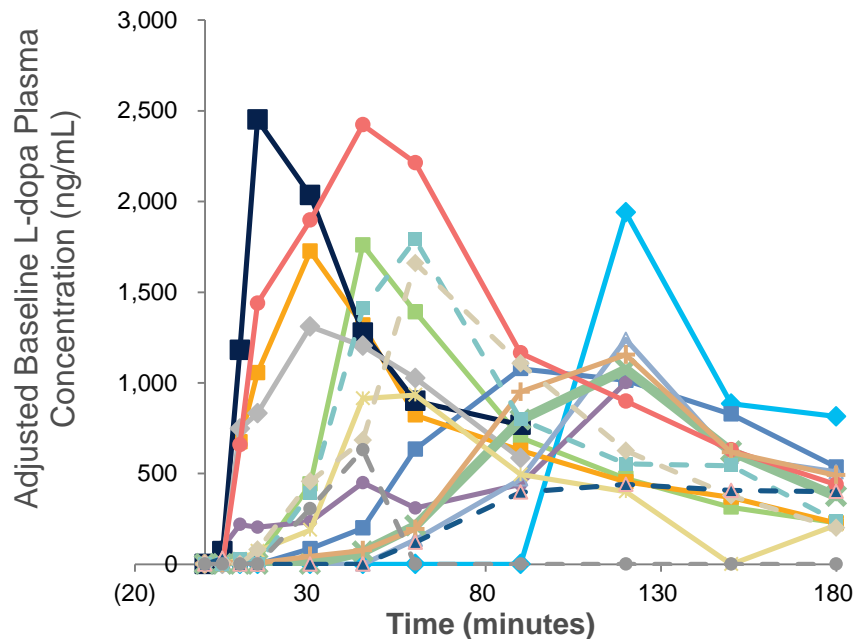
PD related challenges

- Challenges with swallowing
- Reduced involuntary muscle movement, including unpredictable digestion and delayed gastric emptying

Improving the Standard of Care Possible

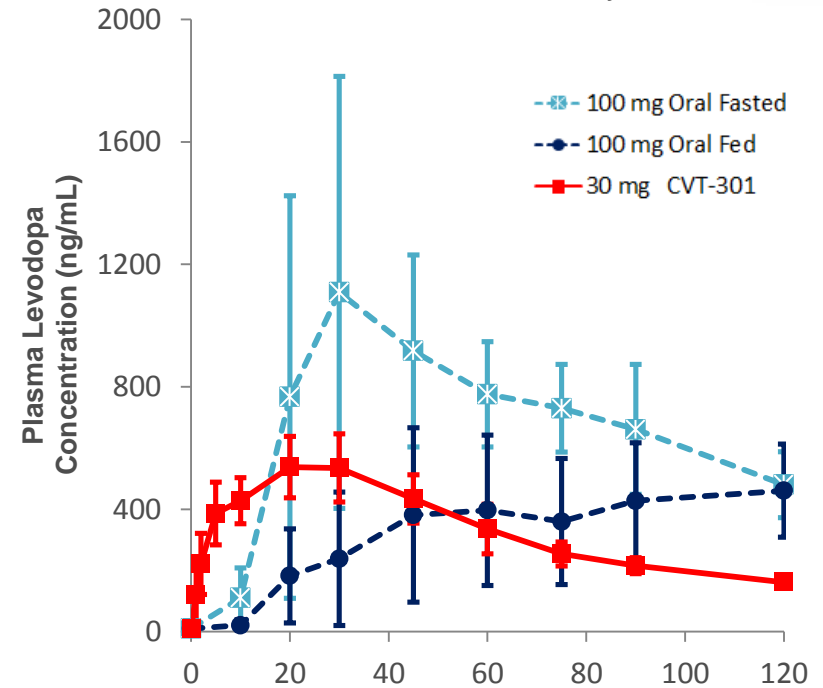
Current Oral Standard of Care

Data from Phase 2a in fasted PD patients



CVT-301 Profile

Data from Phase 1 trial in healthy volunteers



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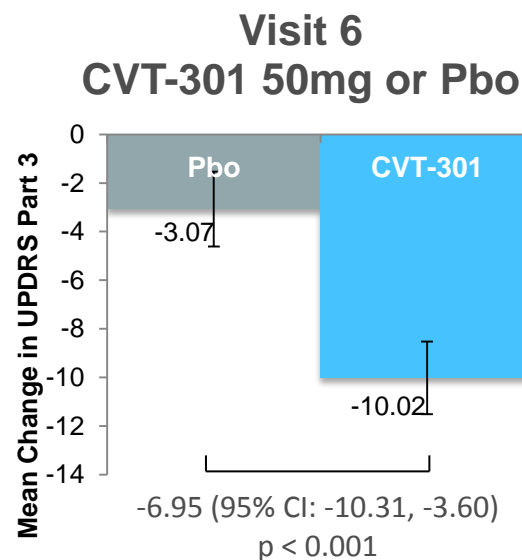
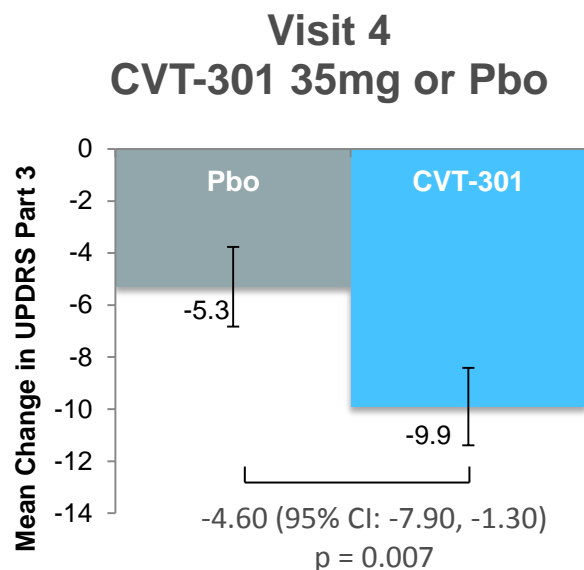
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CVT-301 Overview

- Self-administered, inhaled adjunct therapy to treat OFF episodes
- Device delivers precise doses of dry powder L-dopa
- Clinical results to date have shown potential to rapidly and reliably treat OFFs as they occur
 - Studied in three clinical studies to date
 - Most recent result was a positive phase 2b study, presented at AAN



Phase 2b Study (CVT-301-003) Achieved Primary Outcome Measure



UPDRS Part 3 Clinically Important Differences (CID)*:

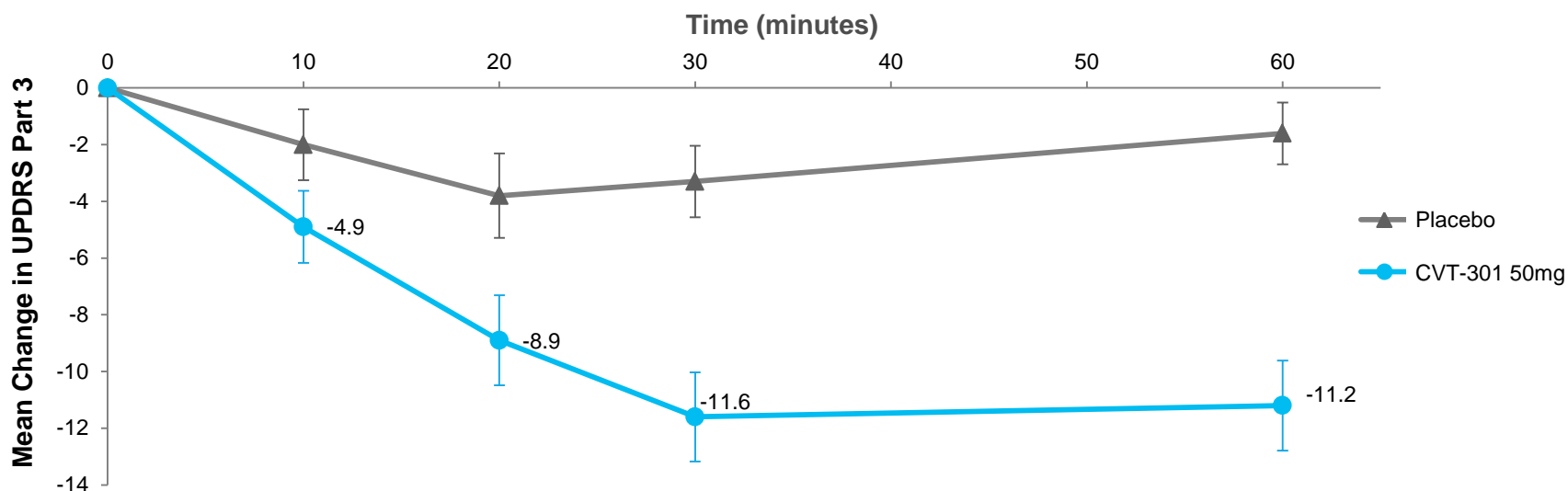
2.5pts = Minimal CID
5.2pts = Moderate CID
10.8 pts = Large CID

* Schulman et al, Arch Neurol. 2010;67(1):64-70

Clinically important reductions at all visits (both tested doses)

Separation vs. Placebo Observed in as Early as 10 Minutes

Visit 6 – CVT-301 50mg dose



	10 min	20 min	30 min	60 min
Diff vs Pbo Mean (SEM)	-3.56 (1.62)	-5.68 (2.04)	-8.43 (1.90)	-9.59 (1.83)
p-value	0.0309	0.0068	<0.0001	<0.0001

UPDRS Part 3 Clinically Important Differences (CID)*:
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 10.8 pts = Large CID

Phase 2b Safety Profile

- Well tolerated with no increase in dyskinesia during at-home use
- There were no serious AEs and the incidence of drug-related AEs was similar between treatment groups
- Lightheadedness was reported in two placebo subjects and three CVT-301 subjects
- Cough was reported for one placebo subject and four CVT-301 subjects - no cough AEs led to dose reduction or withdrawal from the study; all were mild in severity
- There were no observed, treatment-associated adverse effects on lung function

Phase 3 Study Expected to Begin Early 2015

- Primary outcome measure – UPDRS Part III
- Treatment period – 3 months
- Three arm study (placebo/low dose/high dose)
- Approximately 345 subjects
- Each dose delivered in 2 capsule inhalations

Clear Regulatory Path to Market

- One Phase 3 pivotal study efficacy study
- 505(b)2 filing pathway
- Ability to file on a Phase 3 program supported by Phase 2b data
 - Phase 3 efficacy study
 - Safety study w Long Term Extension
 - PK studies in people with asthma or smokers

Commercial Opportunity

- Approximately 350,000 patients in the U.S. may be appropriate for treatment
- Significant overlap with AMPYRA prescribers
- Market research with physicians, payers, and patients indicates a significant unmet need
- Projected US peak sales in excess of \$500M

Multiple Barriers to Entry

- Technology challenges of loading significant amounts of drug through a pulmonary route
- Regulatory challenges with pulmonary drug / device combinations
 - Significant management experience in both delivery technologies and pulmonary drug development
- Extensive patent portfolio

Transaction Summary

- Late stage asset with significant unmet medical need
- Compelling Phase 2b data; Phase 3 study expected to initiate in early 2015
- Leverages ACOR neurological expertise, commercial organization
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Q&A

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