TID PK Study

Nasdaq: NTEC

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Continuous Dopaminergic Stimulation (CDS) Current Concepts

- Fluctuating plasma levodopa levels lead to pulsatile stimulation of striatal dopamine receptors
- Pulsatile stimulation of DA receptors causes:
  - Molecular changes in basal ganglia input neurons
  - Neurophysiologic changes in basal ganglia output neurons
  - Development of motor complications (motor fluctuations and dyskinesia)

Olanow et al, Lancet Neurology 2006

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Continuous Dopaminergic Stimulation (CDS) Current Concepts

- It has been hypothesized that continuous delivery of levodopa will restore brain DA in a more physiologic manner
- Open label and double blind studies confirm that the risk of motor complications is reduced if the same short-acting dopaminergic agent is delivered continuously rather than intermittently

(Olanow et al, Lancet Neurol 2014)

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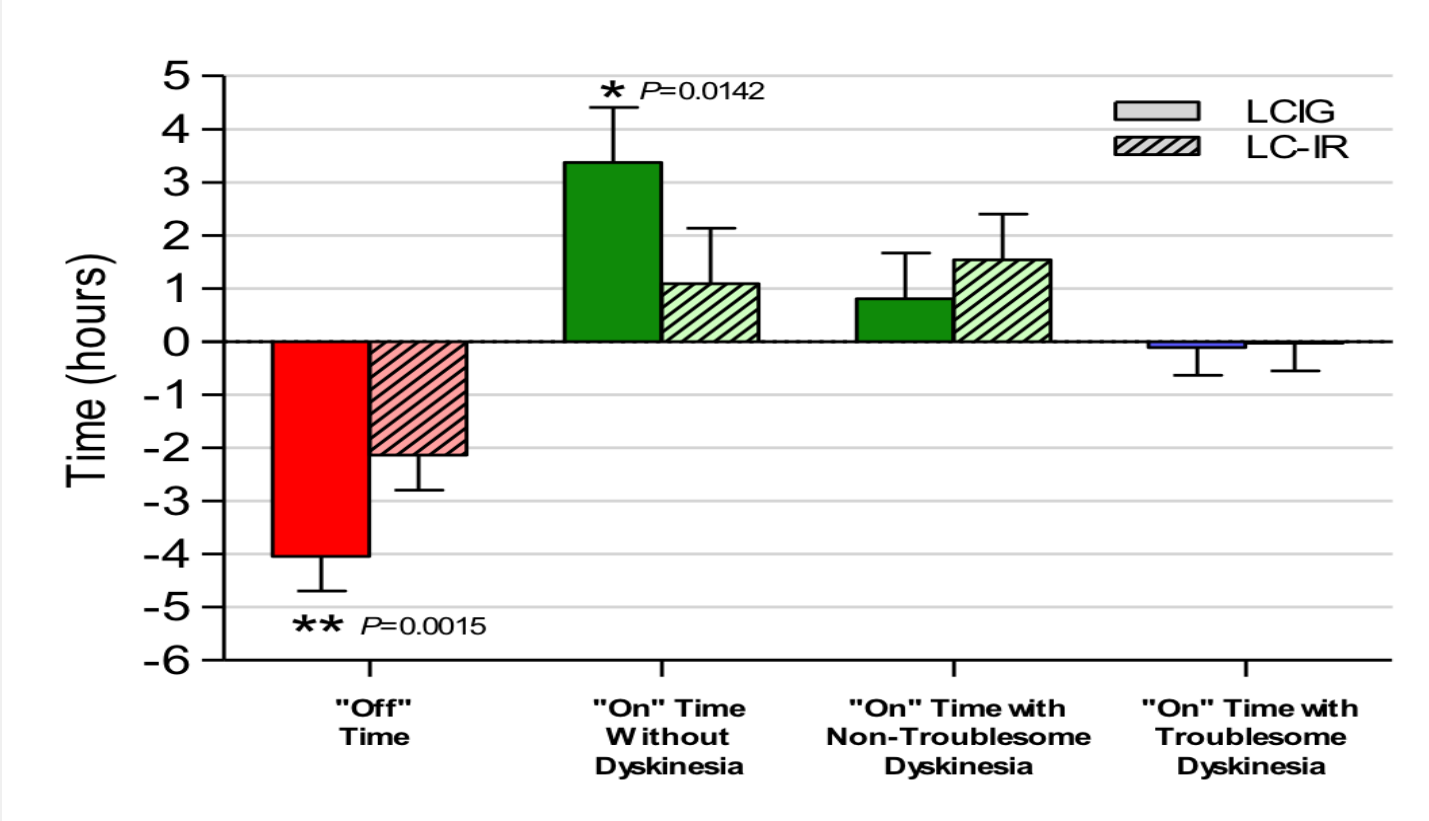
Duodopa® Study – Double-Blind, Double-Dummy. Double-Titration Study



Olanow et al, Lancet Neurol 2014

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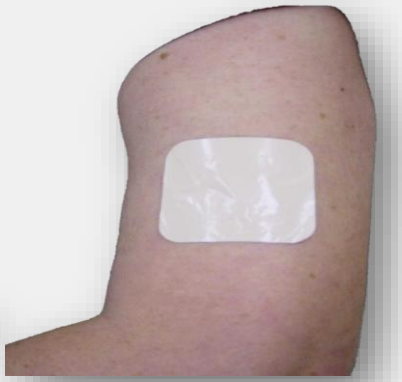
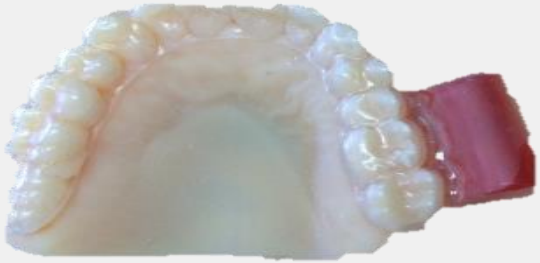
Approaches to CDS in PD Patients

- Continuous intrajejunal infusion
- Continuous patch delivery
- Continuous sc infusion
- Continuous intraoral infusion
- Oral drugs with long t1/2





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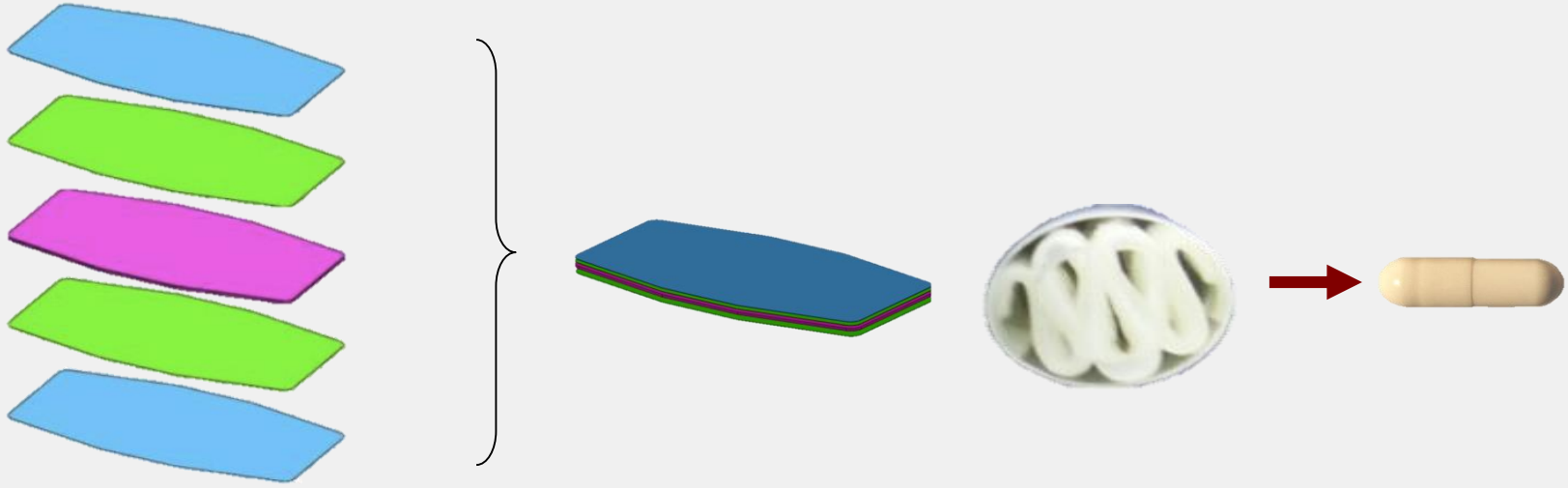
The Accordion Pill™

- Multi-layer, planar structure composed of biodegradable films folded into accordion shape placed into a standard size capsule



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Intec PK Study

- Open label cross-over PK study
- 12 subjects
- PD consistent with UK Brain Bank Criteria
- On stable doses of standard oral levodopa
- Day 1 – arrive in clinic in practically defined OFF state
  - Standard Levodopa PK
- Day 2-7 – treated with AP – CD/LD 50/500 mg tid
- Day 8 - arrive in clinic in practically defined OFF state
  - AP – Levodopa PK

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Intec PK Study – Hospital Protocol

- Day 1 – Levodopa PK-study
  - Standard Levodopa 1.5 25/100mg tabs vid (0, 3, 6, 9, 12 hours)
- Day 8 – AP PK-study
  - AP- CD/LD (Levodopa) 50/500mg tid (0, 5, 10 hours)
- PK evaluations
  - Q 30” from 0 to 16 hours, then at 24 hours

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Intec PK Study - Endpoints

- Primary Endpoint
  - Fluctuation Index (C_{max}-C_{min})/$C_{average}$) in steady state (4-16 hours)
- Sensitivity Analyses
  - Fluctuation Index (4-12 hours)
  - Fluctuation Index – Patients with Complete Data Set
  - Fluctuation index calculated by 2 hr time blocks (0-16 hours)
- Secondary Endpoint
  - Levodopa Coefficient of Variation (SD/$C_{average}$) in steady state (4-16 hours)

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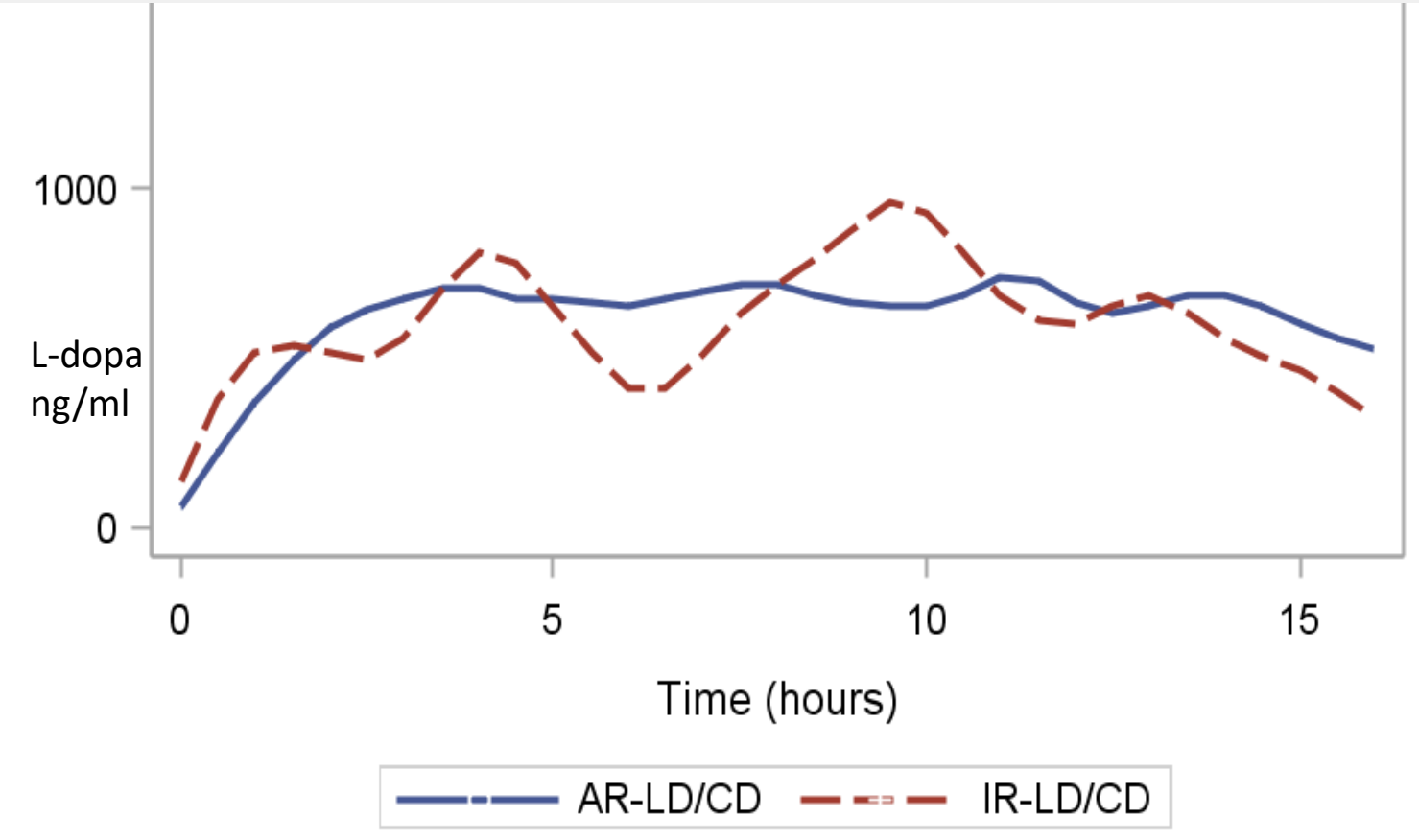
Levodopa Concentration by Time (0-16 hours); Smoothed Splines by Group



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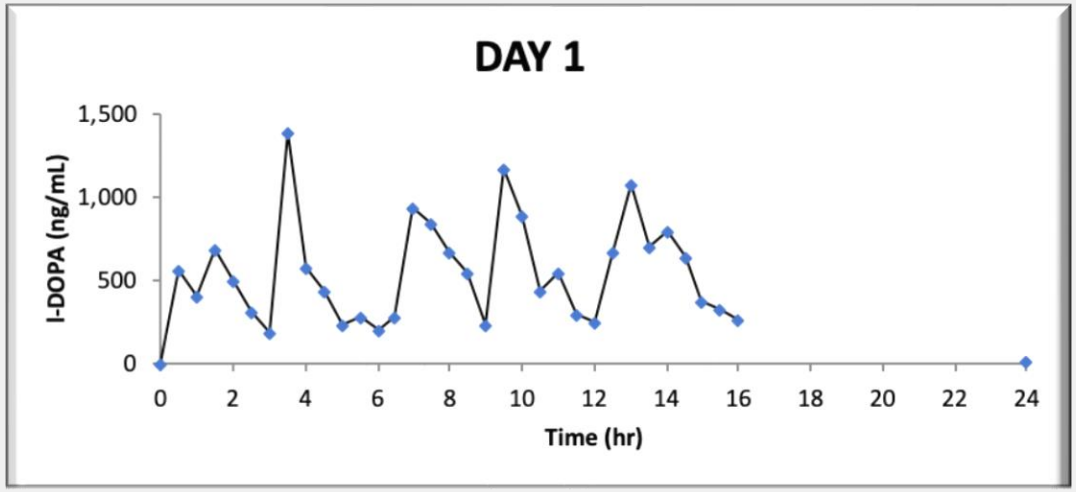
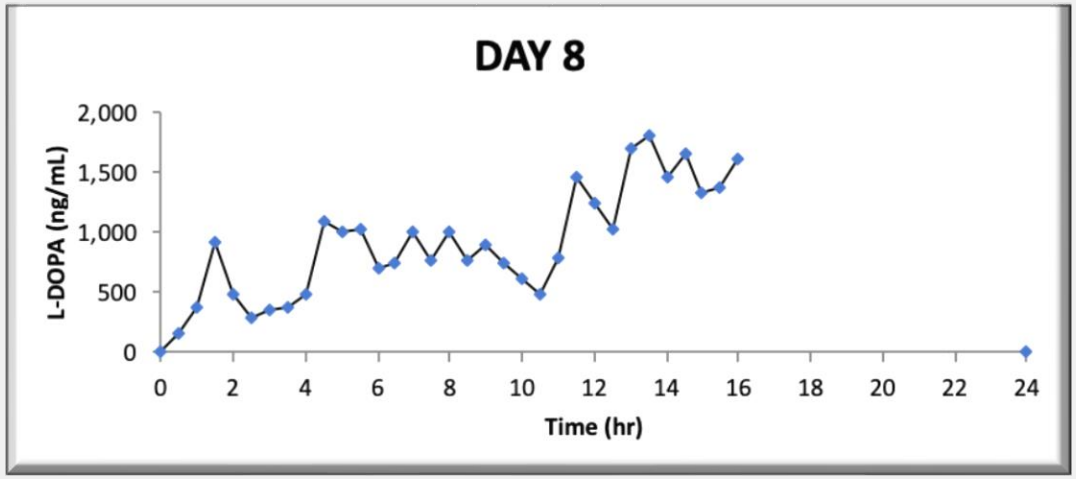
Representative Patient





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Primary Endpoint: Fluctuation Index of Plasma Levodopa Concentration in Steady State

	4-16 hours (primary endpoint)		
Treatment	Mean	95% CI	P-value
IR-CD/LD	2.22	1.82 – 2.62	NA
AP-CD/LD	1.59	1.23 – 1.95	NA
Difference	0.63	0.24 – 1.03	0.005

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Tolerability and Safety

- Tolerability
  - No drop outs
- Safety
  - Day 1: IR-CD/LD PK day
    - Abdominal Cramps – mild
    - Diarrhea – mild
    - Fever
    - Panic attack
  - Day 8: AP-CD/LD PK day
    - No Adverse events reported

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Intec PK Study - Summary

AP-CD/LD met all primary, sensitivity and secondary endpoints

- Primary Endpoint
  - Fluctuation Index P=0.005
- Sensitivity Analyses
  - FI - 0-12 hour steady state P=0.013
  - FI - Completer Data Set P=0.015
  - FI – 2 hour time blocks P=0.001
- Secondary Endpoint
  - Coefficient of Variation P=0.047

AP-CD/LD was safe and well tolerated

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Conclusions

- Treatment with the Accordion Pill™ 50/500 mg tid resulted in reduced plasma levodopa variability in comparison to standard oral levodopa treatment
- Clinical studies indicate that reduced variability in plasma levodopa is associated with a reduced risk of motor complications
  - PK is a surrogate for efficacy
- The effect of the Accordion Pill on motor complications in PD patients is currently being tested in a Phase 3 study

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