CONTINUOUS THERAPY. BECAUSE LIFE GOES ON

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Who we are

New formulations of existing drugs allow new administration routes that overcome current limitations.

New drug with significant clinical advantages.

High NCE-like barriers to entry grant de facto exclusivity.

High price point.

Accelerated lower risk regulatory pathway (505b2), short time to market.
<table>
<thead>
<tr>
<th>Product Candidate</th>
<th>Indication</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Pivotal Phase III/PK</th>
<th>NDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ND0612</td>
<td>Advanced Parkinson’s Disease</td>
<td></td>
<td></td>
<td></td>
<td>LD/CD, Subcutaneous</td>
<td></td>
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<tr>
<td>ND0701 (EU)</td>
<td>Severe Parkinson’s Disease</td>
<td></td>
<td></td>
<td></td>
<td>Apomorphine, Subcutaneous</td>
<td></td>
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<tr>
<td>ND0801</td>
<td>CNS Disease Cognition disorders</td>
<td></td>
<td></td>
<td></td>
<td>Nicotine and Opipramol, Transdermal</td>
<td></td>
</tr>
<tr>
<td>ND0901</td>
<td>Parkinson’s Disease</td>
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</table>
ON/OFF time

Parkinson’s disease patient with severe dyskinesia
Almost all patients develop fluctuations within 5 years.

The brain needs steady levels of dopamine.

Oral levodopa quickly disintegrates in the blood and loses its effect.

Instead of steady levodopa levels – oral levodopa creates fluctuations.

The greatest challenge of levodopa therapy:

**Continuous delivery**

Blood Levels of Levodopa

Dyskinesia

“On” Time

“Off” state

Fluctuations

Levodopa Administration

ND0612

Levodopa, the Gold Standard, has a major drawback: short half-life.
Efforts to improve continuous LD therapy - Limited success

Attempts to achieve continuity...

...but no Game Changers: Why?

LD has only existed to date in solid form that must be administered through the GI tract

Why has LD not been developed to enable alternative routes of administration that provide better continuity?

Because it was thought impossible; previous attempts to formulate LD into liquid forms have failed

NeuroDerm is the first to formulate LD into a liquid formulation
Advanced Parkinson’s patients face highly invasive treatment alternatives

<table>
<thead>
<tr>
<th>Deep brain stimulation</th>
<th>Intra-duodenal LD/CD pump (Duopa/Duodopa)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Removal post infection</strong></td>
<td><strong>Seizures</strong></td>
</tr>
<tr>
<td>~15%</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

**Device sales:** ~$500M (excluding surgery)

**Cost per patient:** up to 100,000 1st yr, ~$25,000 yr/5yr

**Sales:** ~$300M

**Cost per patient:** ~$80,000/yr (US)
ND0612
A subcutaneous alternative to continuous LD infusion

ND0612 H
Severe PD
The 1st liquid LD/CD alternative to surgical treatments
Day and night treatment
720mg (2x6 ml) LD/24 hrs
Device – available
>350,000 patients US and EU

ND0612 L
Moderate PD
The 1st liquid LD/CD drug
Day and night treatment
270mg (4.5ml) LD /24 hrs
Device – available
> 900,000 patients US and EU

ND0612 L
Moderate PD
2nd generation delivered through a patch pump
Day and night treatment
270mg (4.5ml) LD /24 hrs
“One and done” operation
Device in development
Clinical development
Phase I and Phase IIa

ND0612L achieves steady LD levels with dose proportionality

Phase I

![Graph showing mean plasma LD concentration over time after infusion initiation for different infusion rates.](image)

- **Mean Plasma LD Concentration (ng/ml)**
  - 80 µl/h
  - 120 µl/h
  - 160 µl/h
  - 200 µl/h
  - 240 µl/h

- **Time after infusion initiation**: 15 to 24

- **n=30**
ND0612L Phase II study design

**Randomization**
- 30 moderate to severe patients 2:1

**Oral SOC**
- ND0612L+oral SOC
  - Period 1: Randomized double blind 2 weeks
  - Placebo + oral SOC

**Pre-Randomized**
- 16 patients 1:1

**ND0612L**
- Period 2: Open, 1 week

**ND0612L+Ent**

**Primary endpoints**
- Safety
- Tolerability
- PK

**Secondary endpoints**
- LD dose adjustment
- Pump usability

**Exploratory efficacy endpoints**
- OFF time
- ON time w/o troublesome dyskinesia
- AIMS
- Quality of sleep (PDSS)
- Quality of life (PDQ-39)
- Disease severity (CGI-C)
Study 003: first period pharmacokinetics
ND0612L stabilizes LD plasma concentration above an average of ~800ng/ml

ND0612L transforms levodopa PK in PD patients
Study 003 - second period pharmacokinetics
ND0612L stabilizes LD plasma concentration

An average steady plasma levodopa concentration of 550ng/ml was maintained with ND0612L alone, and 800ng/ml when combined with oral entacapone.

ND0612L transforms levodopa PK in PD patients.
Study 003 results: ND0612L reduces OFF time w/o increasing dyskinesia (in clinic)

Improves motor fluctuations without “paying the penalty” of troublesome dyskinesia

**OFF time**

- Change from baseline (hr)
- Placebo (n=11) vs. ND0612L (n=18)
- 2 Hours reduction in OFF time
  - 41% vs. 9% in the placebo

**Troublesome dyskinesia**

- Change from baseline (hr)
- Placebo (n=11) vs. ND0612L (n=18)
- Reduction in troublesome dyskinesia
Study 003 results: ND0612L improves quality of sleep, quality of life and global clinical disease severity

**Quality of sleep**
- Mean change in PDSS score: ND0612 (n=19) vs. Placebo (n=11)
- ND0612: -17.13 vs. Placebo: -0.5
- 30% improvement in quality of sleep compared to placebo

**Quality of life**
- Mean change in PDQ-39 score: ND0612 (n=19) vs. Placebo (n=11)
- ND0612: -6.6 vs. Placebo: -1.78
- 17% improvement in quality of life compared to placebo

**Global clinical improvement**
- % of patients improved (CGI-C score)
- ND0612 (n=19): 90%
- Placebo (n=11): 36%
- 90% improvement in disease severity compared to placebo
Phase IIa results: ND0612H reaches high LD plasma levels

Steady ND0612H levels alone and with oral entacapone (1x/4h)

<table>
<thead>
<tr>
<th>Plasma LD (ng/ml)</th>
<th>Alone</th>
<th>With entacapone</th>
</tr>
</thead>
<tbody>
<tr>
<td>ND0612L</td>
<td>487</td>
<td></td>
</tr>
<tr>
<td>ND0612H</td>
<td>1,454</td>
<td>1,844</td>
</tr>
</tbody>
</table>

Steady ND0612H - Average of all patients

Time (hr) 0 1 2 3 4 5 6 7 8
Plasma LD (ng/ml) Oral LD/CD ND0612 60/7.5 mg/mL ND0612 60/14 mg/mL ND0612 60/14 mg/mL +Entacapone
Pilot PK results: ND0612H achieved comparable PK to Duodopa® within BE acceptance criteria

- AUC - bioequivalent  
  (90% CI within the BE criteria)

- $C_{\text{max}}$ - bioequivalent  
  (90% CI within BE criteria)

- Shape of the curve - similar

Additionally, ND0612H:

- Conformed to levels obtained in study 004 in advanced PD patients
- Had lower inter and intra-subject variability (CV%) than Duodopa®
- Had higher bioavailability than Duodopa

35 subjects out of 36 completed the study
ND0612H Phase II 006 study: Open-label, blind rater

1:1 Randomization
38 PD patients

Primary endpoint:
Change from baseline to day 28 in daily OFF-time (normalized to 16 waking hours) as assessed by a blinded rater.

Screening Period
Up to 28 days

Regimen 1 – ND0612H 24 hrs
Regimen 2 - ND0612H 14 hrs + oral LD in the morning

Secondary endpoints:
Safety and tolerability

Key secondary endpoints:
Percentage of subjects who were “ON” by 8:00am and 9:00am
006 Results - OFF time decreased, Good ON increased

**Primary endpoint - OFF**
- R1 - decreased by 2.8 hours (P=0.004)
- R2 - decreased by 1.3 hours (P=0.158)

**Secondary endpoint - Good ON**
defined as “ON” with no or mild dyskinesia
- R1 - increased by 3.7 hours (p < 0.001)
- R2 - increased by 2.8 hours (p = 0.003)
Key secondary endpoint – morning akinesia
Patients ON at 8AM & 9AM (R1)

Patients ON at 8:00AM increased from 11% at baseline to 50% by day 28 (P=0.020)
(key secondary EP, patient assessment)

Patients ON at 9:00AM increased from 32% at baseline to 75% by day 28 (P=0.007)
(key secondary EP, patient assessment)
Regimen 1 (R1)
UPDRS III Score decreased (Motor skills increased)

UPDRS III Score at 8AM decreased by 45% (17 points), and remained lower than baseline throughout the day.
ND0612H Phase II 006 responder analysis (post-hoc): Complete reduction of OFF time to zero

8/19 (42%) of R1 patients achieved complete resolution of OFF time to zero hours
ND0612H Phase II 006 responder analysis (post-hoc):
Reduction in troublesome dyskinesia and oral LD dosing

**Troublesome dyskinesia (TBD) >1h**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Type</th>
<th>Baseline</th>
<th>Change</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Troublesome dyskinesia* (R1+R2) (n=14)</td>
<td>Post-hoc</td>
<td>5.1 hr</td>
<td>Decreased by 3.5 hr</td>
<td>p=0.011</td>
</tr>
</tbody>
</table>

* Sub group of patients with TBD > 1hr

**Oral LD dosing and frequency**

The average dose of oral LD decreased from approximately 1100mg at baseline to approximately 330mg.

![Graph showing oral LD dosing frequency](image)

R1+R2: Oral LD dosing frequency

<table>
<thead>
<tr>
<th>Daily dosing frequency</th>
<th>Baseline</th>
<th>Day 28</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
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<tr>
<td>4</td>
<td></td>
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<tr>
<td>5</td>
<td></td>
<td></td>
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<tr>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Study 006 results: ND0612H improves quality of sleep, quality of life

<table>
<thead>
<tr>
<th>Sleep Quality</th>
<th>R1</th>
<th>R2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in PDSS score from baseline</td>
<td>-4.1</td>
<td>-0.8</td>
</tr>
<tr>
<td>p=0.042</td>
<td>p=0.679</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality of Life</th>
<th>R1</th>
<th>R2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in PDQ39 from baseline</td>
<td>-7.51</td>
<td>3.66</td>
</tr>
<tr>
<td>p=0.008</td>
<td>p=0.161</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Global improvement</th>
<th>R1</th>
<th>R2</th>
</tr>
</thead>
<tbody>
<tr>
<td>by subject on day 28</td>
<td>78%</td>
<td>79%</td>
</tr>
</tbody>
</table>
ND0612 - Good safety profile

003 study ND0612L:

- Draize score slightly elevated, slight pruritus, similar in both groups
- SC nodules (0.5-1cm) resolving spontaneously
- No particular systemic AE
- No patient discontinued early
- Local safety – similar to Phase I
- No patient discontinued early

006 study ND0612H:

- Infusion site reactions (nodules, bruising and erythema) were common yet generally well-tolerated
- Nodules were typically undetected visually (only by deep palpation); hematomas were detected visually
- Hematomas and nodules did not pose safety risk and resolved spontaneously
- 33 subjects (87%) out of 38 completed the study
- 5 did not complete the study
Development plan
Development timelines – ND0612

- **2017**
  - Definitive PK studies

- **2018**
  - NDA submission

- **2019**
  - Ongoing Long-term safety, 012 (~150 patients*) - “Beyond” study

- **Study 007 (240 patients) - “iNDiGO” study**
  - MAA submission

*Note: ND0612 development timeline highlights key milestones in the clinical trial process, including definitive PK studies, NDA submission, ongoing long-term safety studies, and MAA submission.
Commercial development
Advanced PD patients - a hidden segment with the largest unmet need

Breakdown by severity (2011)

- Severe: 16%
- Mild: 42%
- Moderate: 42%

One in one hundred people over age 60
>6 million PD patients WW

Moderate to severe PD
~60% of all patients

PD drug sales market $3.8B
Drugs: ~$3.3 B; many are generic
Devices: <1% of PD patients are treated
Cost of drugs for moderate patient: ~$6,000/yr
Cost of treatment for severe patient: ~$80,000/yr
Only ~1% of PD patients in the US and EU are treated by advanced treatments but spend approx. $800M* (excluding surgery).

<table>
<thead>
<tr>
<th>Segment</th>
<th>US &amp; EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total PD patients</td>
<td>2,200,000</td>
</tr>
<tr>
<td>Moderate PD patients</td>
<td>~900,000</td>
</tr>
<tr>
<td>Severe PD patients</td>
<td>~350,000</td>
</tr>
<tr>
<td>DBS new patients/yr</td>
<td>~22,000</td>
</tr>
<tr>
<td>Duodopa/Duopa patient base</td>
<td>~3,500</td>
</tr>
<tr>
<td>Duodopa/Duopa new patients/yr</td>
<td>~700</td>
</tr>
<tr>
<td>Apomorphine patient base**</td>
<td>~4,000</td>
</tr>
<tr>
<td>Severe patients not treated with advanced treatments</td>
<td>~&gt;300,000</td>
</tr>
</tbody>
</table>

* DBS, Duopa/Duodopa and continuous apomorphine

** Continuous apomorphine treatment
U.S. payers – pricing expectations

Payers expect that ND0612H will be priced relative to alternative treatments requiring surgery

ND0612H comparable price

Duopa/Duodopa DBS

Duopa/Duodopa Cost per year*: ~$80,000/year

DBS cost 1st year: Up to $100,000

ND0612H

According to dosage (price per mg) at a ratio of 1:2.7

ND0612L comparable price

Payers expect that ND0612L will be priced per milligram relative to ND0612H, i.e. at approx. 35%-40% of ND0612H price

Source: A company sponsored third-party market research report of 34 neurologists and payers in the US and EU, December 2015, ZS Associates.
PD gatekeepers

Dozens of KOLs
1500 Movement Disorder Specialists*
14K Neurologists**/***/#

ND0612H
Number of treating physicians

ND0612L
Number of treating physicians

Source: *Dr. Olanow, President, MDS; **Association of American Medical Colleges; ***Neurology Atlas, WHO, 2004; #Neurology Residency Training in Europe—the Current Situation
ND0612L and ND0612H – physician perspective
Summary of a qualitative physician survey

- Moderate patients typified by:
  - Burdensome oral dosing
  - Younger age/earlier disease stage

- Severe patients requiring lower LD dose

“~50% of all PD Patients”

ND0612L

- Severe patients typified by:
  - Multiple OFF episodes
  - Ineffective oral therapies
  - Higher levodopa dose requirement
  - Complicated treatment regimen

“~20% of all PD Patients”

ND0612H

Source: A company sponsored third-party market research report of 12 neurologists in the US, Mat 2014, Trinity Partners.
Physicians perceive ND0612L as a substitute to DBS

- **DBS offered to ~10% of patients:** Only ~2% to ~5% agree due to the invasive nature relative to an oral medication

- **Patients referred for DBS are:** Younger, healthier, cognitively intact, of moderate severity with multiple oral medications

Source: A company sponsored third-party market research report of 12 neurologists in the US, May 2014, Trinity Partners.
Email Reporting on a visit to a PI

...He saw at the clinic today a 012 patient who came to the M1 Visit, and was excited to see that the patient has no OFF time at all and no dyskinesia! This was a very severe patient that needed his wife to turn him in bed at night, and get him out of bed at night to urinate and now he is independent and has zero OFF, with no dyskinesia. XXXX said "This visit made my day, and you should know you have a very good drug."

Source: Study 012 clinical trial physician
Commercially available apomorphine
High efficacy – major limitations

Continuous SC apomorphine, available outside the US, is indicated for advanced PD patients who do not respond well to levodopa

- Highly effective
- Rapid onset (3-5 minutes)

- Low local tolerability and high local pain
- Large daily volume
- 12hr infusion limit per injection site - inconvenient
- no night treatment

Up to 70% of dropout in the clinical trials with commercial apomorphine was due to local site reaction (Ribaric., 2012)

Photograph of abdomen with apomorphine infusion (Hazel et al., 2008)
ND0701 overcomes major limitations of current commercial apomorphine

- New proprietary apomorphine-base concentrated formulation
  - vs. apomorphine HCl in current commercial products

- Small volume enables delivery through discrete patch pump

- Superior local safety profile

- Regulatory path
  Hybrid submission (bioequivalence with the reference listed drug - Apo-Go®)
ND0901

A new drug-device candidate for continuous subcutaneous LD/CD delivery

Comprising a novel, concentrated aqueous LD prodrug

Potential target indications
- Treatment of PD in patients with motor fluctuations
- Prevent and delay Parkinson’s disease complications

LCM

A follow-on, life cycle management product to ND0612

Clinical development anticipated to start by early 2018

2018