



Company presentation

2009 Annual report – 11 March 2010, Nordea Markets

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Forward looking disclaimer



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- 2009 Annual report
 - Highlights and financials

- NeuroSearch – Business and strategy

- Key products
 - Huntexil® for Huntington’s disease – Orphan drug showing strong results in Phase III
 - Tesofensine – Highly efficacious obesity drug candidate
 - Other product candidates:
ABT-894 (ADHD), ACR343 (schizophrenia) and ACR325 (Parkinson’s dyskinesias)

- 2010 Expected milestones

2009 Annual report
Highlights and financials

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Highlights 2009 – Partnering and financing



- New partner agreements: pipeline inflow and additional financing
 - GSK; expansion of development portfolio under alliance
 - Lilly; three-year CNS drug discovery and development alliance
 - Janssen; three-year CNS drug discovery and development alliance
- Successful completion of a share offering with net proceeds of DKK 400 million

**In 2009, NS added a total of approx.
DKK 900 million to its capital resources**

Highlights 2009 to March 2010

– Pipeline achievements



➤ Huntexil®

- Completed enrolment of 437 Huntington's patients in European Phase III study (the MermaiHD study)
- Positive top line results from the MermaiHD Phase III study
- The North American HART study; compassionate use; pre-launch preparation

➤ Tesofensine:

- Successful End-of-Phase II meeting (FDA) and Phase III preparation

➤ ACR325: Start of clinical Phase IB study in Parkinson's dyskinesia

➤ ACR343: Completion of Phase I and preparation for Phase II (Schizophrenia)

➤ NSD-721: Start of Phase I under the alliance with GSK + funding (EUR 9m)

➤ NSD-788: Completion of Phase I and POM studies with positive results

2009 Financial results and 2010 guidance



NeuroSearch Group (DKK million)	2009	2008
Revenue	85	67
Total costs	(441)	(433)
Operating loss	(356)	(366)
<i>Financial guidance</i>	~ (350)	~ (400)
Net financial income/(expense)	25	(21)
Associated companies	(13)	(19)
Gains/(losses) financial assets	13	(10)
Tax	44	34
Net result after tax	(287)	(382)
Cash position	968	481

2010 guidance: An operating loss of ~ DKK 400 million

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Business and strategy

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NeuroSearch – Key business points



Late stage products

- Huntexil® for Huntington's disease: Significant effects shown in Phase III study (the MermaiHD study) – Pivotal programme ongoing
- Tesofensine for obesity: Best in class drug candidate - Phase III ready

Pipeline

- 8 novel drugs in clinical development & several preclinical candidates – almost half is covered by partner alliances
- Continuous pipeline inflow from own drug discovery and via late-stage M&A

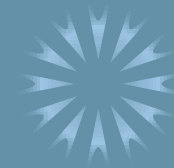
Company fundamentals

- Broad based CNS R&D platform - 220 employees in Denmark and Sweden
- Capital resources of EUR ~135m and strong partners; GSK, Eli Lilly, Janssen & Abbott

Building a CNS speciality pharma

- Huntexil®
 - A unique orphan drug opportunity with all commercial rights retained
- Paving the way for a near term company transformation with a view to sustainable profits from own product sales

Pipeline



Indication	Programme	Mechanism of action	Partner	Preclin.	Phase I	Phase II	Phase III	Market reg.
Huntington's disease	Huntexil®	Dopaminergic stabil.						
Obesity	Tesofensine	Monoamine RI						
ADHD	ABT-894	NNR modulator	Abbott					
Schizophrenia	ACR343	Dopaminergic stabil.						
Parkinson dyskinesias	ACR325	Dopaminergic stabil.						
Cognitive dysfunctions	ABT-560	NNR modulator	Abbott					
Depression/anxiety	NSD-788	Monoamine RI	GSK					
Social anxiety disorder	NSD-721	GABA modulator	GSK					
Preclinical candidates			GSK, Lilly Janssen					

NeuroSearch

- Building a speciality pharma company



Speciality CNS products

Programme	Indication	Partner	Development stage
Huntexil®	Huntington's disease		End of Phase III
ACR343	Schizophrenia		Ready for Phase II
ACR325	Dyskinesias (PD)		Phase Ib

Portfolio of novel preclinical drug candidates

Products for larger CNS based indications (GP driven)

Programme	Indication	Partner	Development stage
Tesofensine	Obesity		Ready for Phase III
ABT-894	ADHD	Abbott	Phase II
ABT-560	Cognitive dysfunctions	Abbott	Phase I
NSD-788	Anxiety/depression	GSK	Phase I
NSD-721	Social anxiety disorder	GSK	Phase I

Huntexil® - Building expertise in:

Regulatory processing

Marketing and sales

Leveraging from the launch of Huntexil®

Specialty CNS drug franchise

Sales revenue

In addition, NeuroSearch will continuously seek to partner products for larger CNS indications and non-CNS indications

Royalties

Huntexil® for Huntington's disease

A unique orphan drug opportunity

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What is Huntington's disease (HD)?



A fatal, hereditary neurodegenerative disorder,

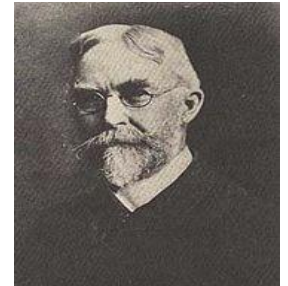
- Causing cell death and circuit disruptions in several brain centres

Symptoms onset most often around 30-50 yrs of age

- Serious motor implications: progressive loss of voluntary movement ability + involuntary movements
- Cognitive impairment
- Psychiatric and behavioural changes

Progresses with a 10-20 yrs life expectancy after symptoms onset

HD patients in the mid and final disease stages require extensive round-the-clock care



Huntington's disease has serious negative implications on quality of life for patients and their families

Huntexil[®] – Highly attractive product proposition



A novel drug for Huntington's disease

- An unexploited market potential: A severe disease with high unmet medical needs
 - ~ 70,000 affected patients in NA/Eu
 - No effective treatment or symptoms relief - and only very few drugs in development
- Orphan drug designation (FDA and EMA)
- Promising target product profile
 - Significant improvement of motor function: effect on both voluntary and involuntary movements
 - Good safety profile and no worsening of other disease signs or symptoms
 - Potential disease modifying properties
- Limited sales force to cover the markets in NA/Eu
- Global commercial rights retained and IP protection until 2020 + 2-5 years extension

Huntington's disease – The market



- In NA/EU, disease prevalence is estimated at 1:10,000 (5:10,000 including people at risk of carrying the gene)
- Estimated number of affected Huntington's patients in NA and EU: ~70,000
- In other populations of European descent, prevalence is similar to that of NA/Eu: 1:10,000 (Australia, Russia, SA and SAf)

Source : Stanford University Huntington's Outreach project (HOPES), the HDSA, the Huntington's Society of Canada



- Prevalence study from 1992 indicating 1: 12,000-25,000 with diagnose based solely on family history and chorea (*Harper et al.*)
- Genetic testing from 1993 has increased the rate of diagnose (still only few choose diagnosis)
- About 13% of patients with confirmed CAG expansion do not have a known family history (seen also in MermaiHD study)
- Results from 9 yrs of genetic testing shows incidence and mutation rates 2 to 3 times higher than previously reported (*Ramos-Arroyo et al., J Neurol Neurosurg Psychiatry, 2004*)

Huntexil® for Huntington's disease

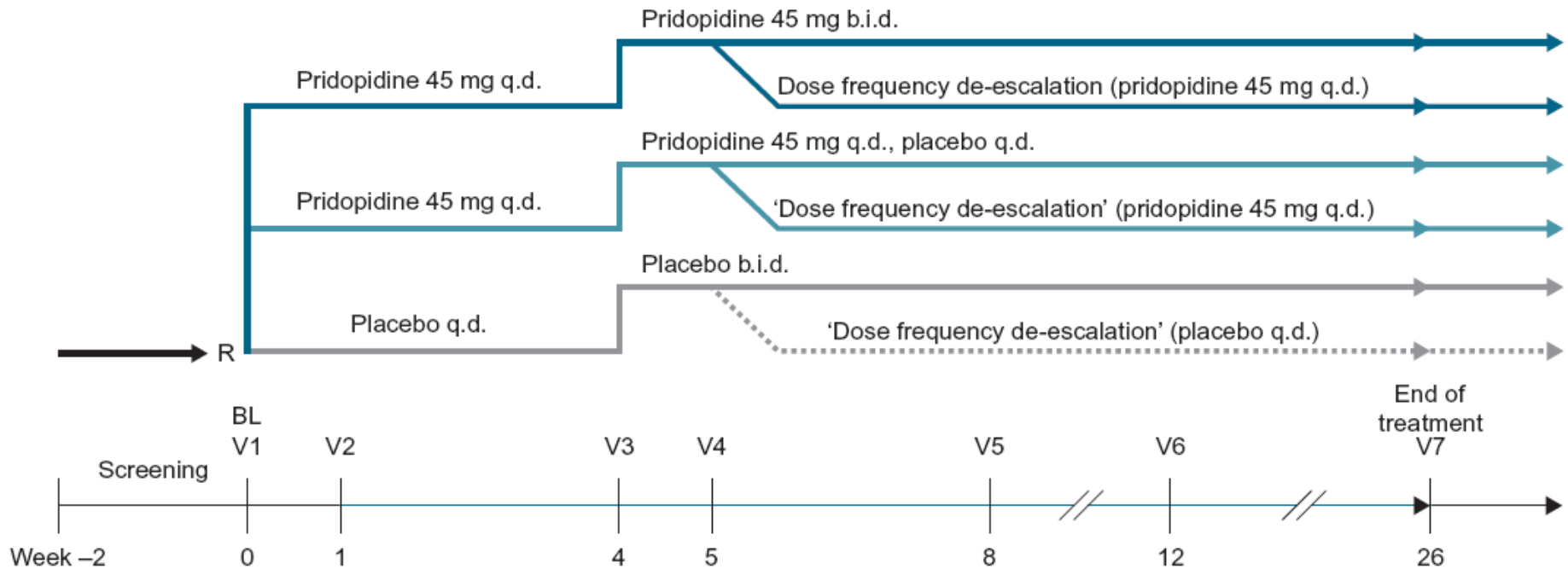
Positive results of the MermaiHD study, a pivotal Phase III study

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The MermaiHD study - Design



- A 26 weeks randomized, double-blinded, parallel-group study, comparing Huntexil[®] 45 mg once daily or twice daily versus placebo for the symptomatic treatment of HD



BL = baseline; b.i.d., = twice daily; q.d. = once daily; R = randomization; V = visit.

Study population – Characteristics



- Aged between 30 and 86 years, mean = 50.6 years
- 215 male, 222 female
- Anti-psychotic medication
 - On: 190 patients (43.5%)
 - Not on: 247 patients (56.5%)
- Mean CAG repeat = 44.7 (between 36 and 63)
- Baseline mean time since diagnosis = 4.8 years (between 0 and 20 years)

The MermaiHD study - Compliance and safety



- Randomised patients, ITT population = 437 (100%)
 - Placebo= 144; 45 mg QD= 148; 45 mg BID= 145

- Completers: 92%
 - Placebo= 129 (90%); 45 mg QD= 143 (97%); 45 mg BID= 131 (90%)

- Withdrawals due to AE = 17 (4%)
 - Placebo= 8 (6%); 45 mg QD= 2 (1%); 45mg BID= 7 (5%)

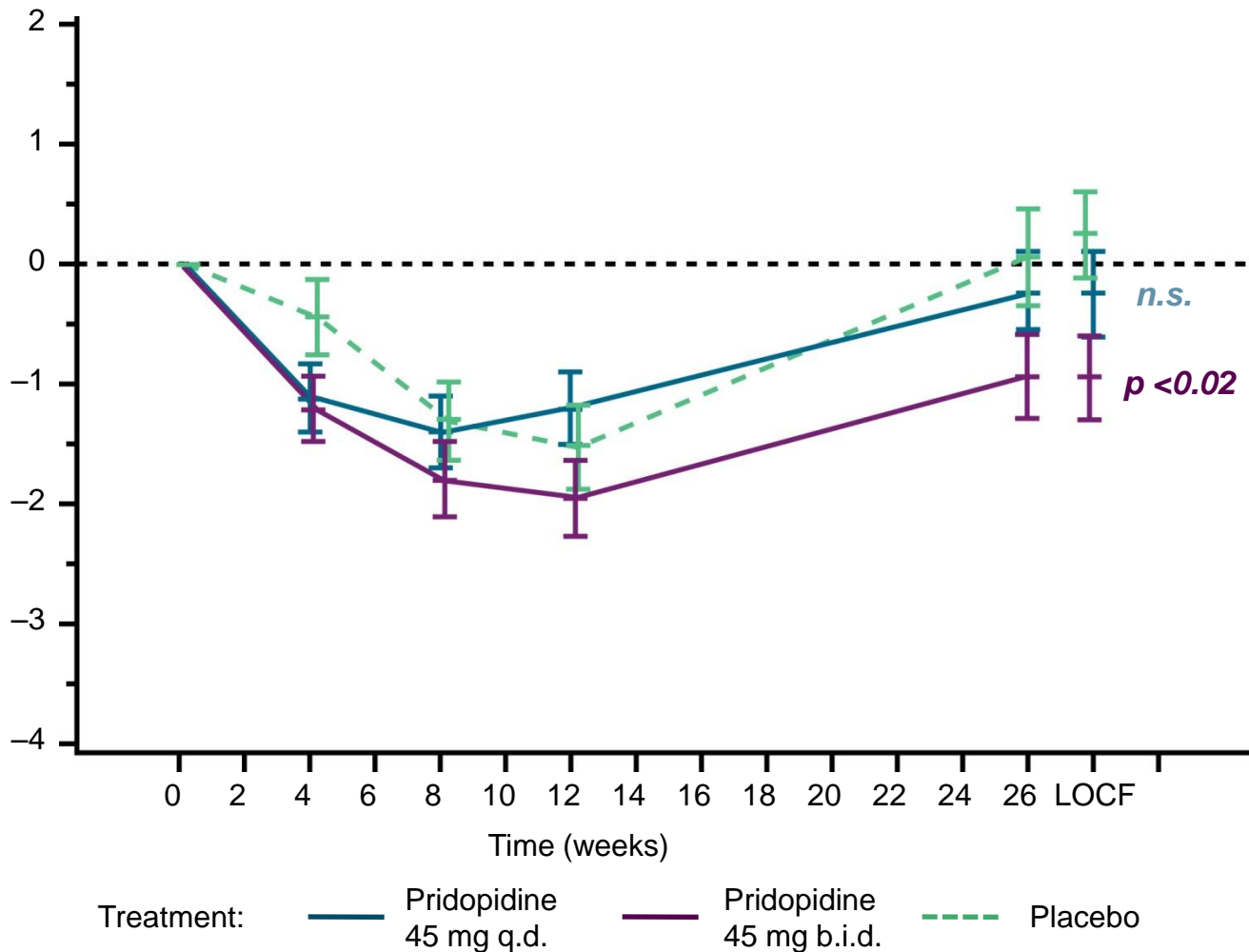
- AEs similar across study arms

- Completers in full compliance, PP population = 82% (357)

Primary endpoint: Significant improvement of voluntary movements (mMS)



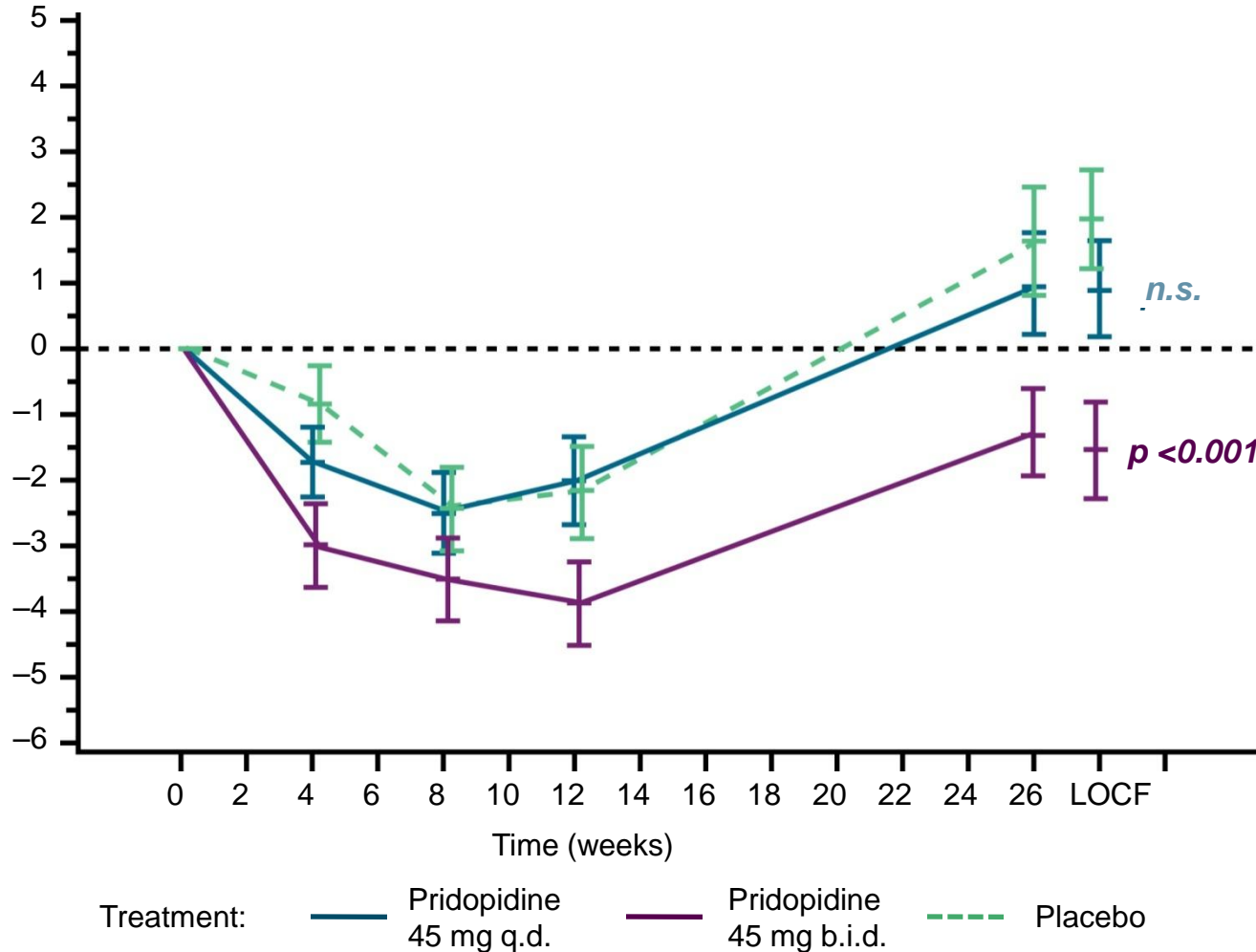
Full analysis set (ITT population)



Significant improvement of global motor function (TMS)



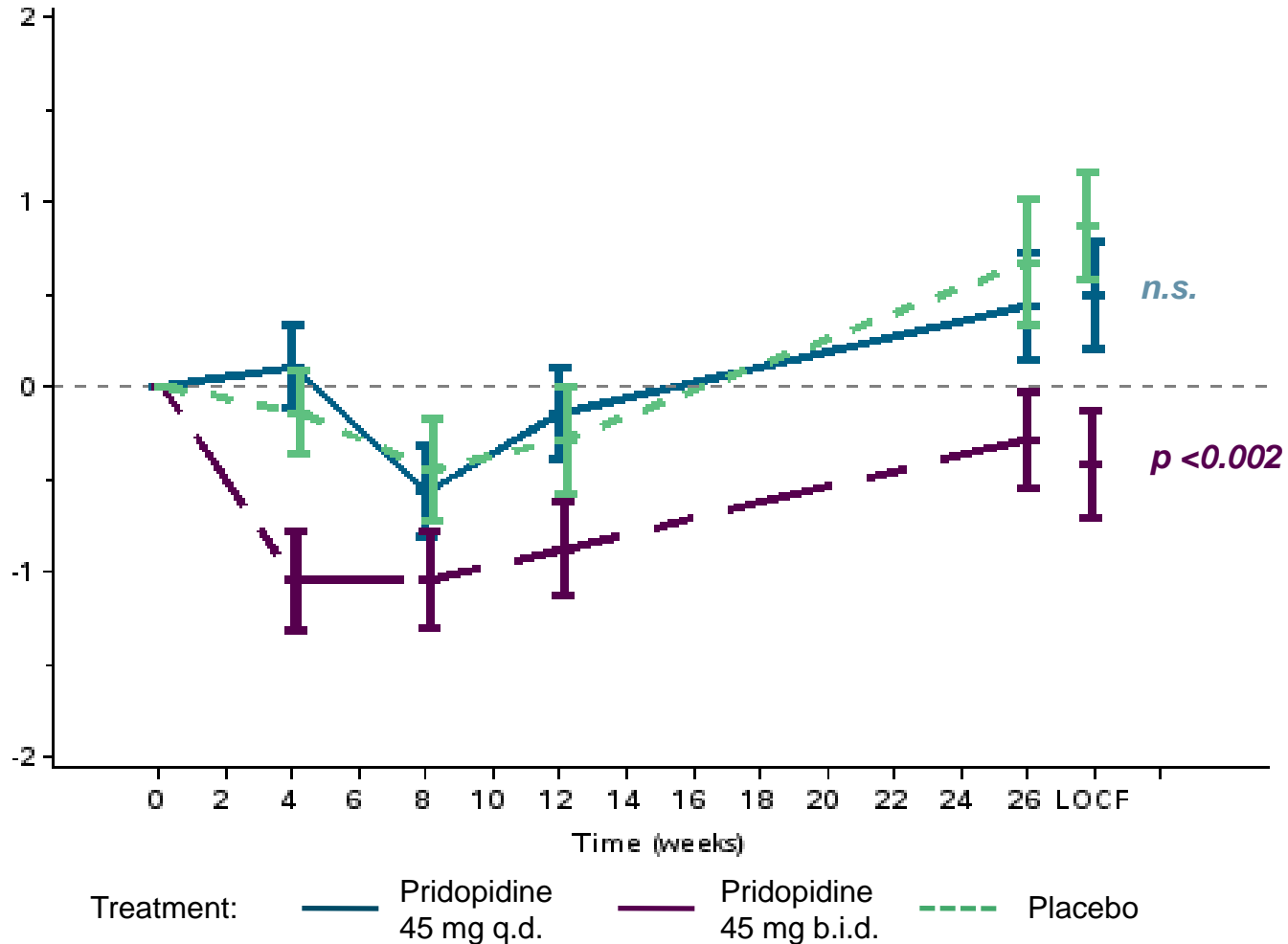
Full analysis set (ITT population)



Significant improvement of Eye movements



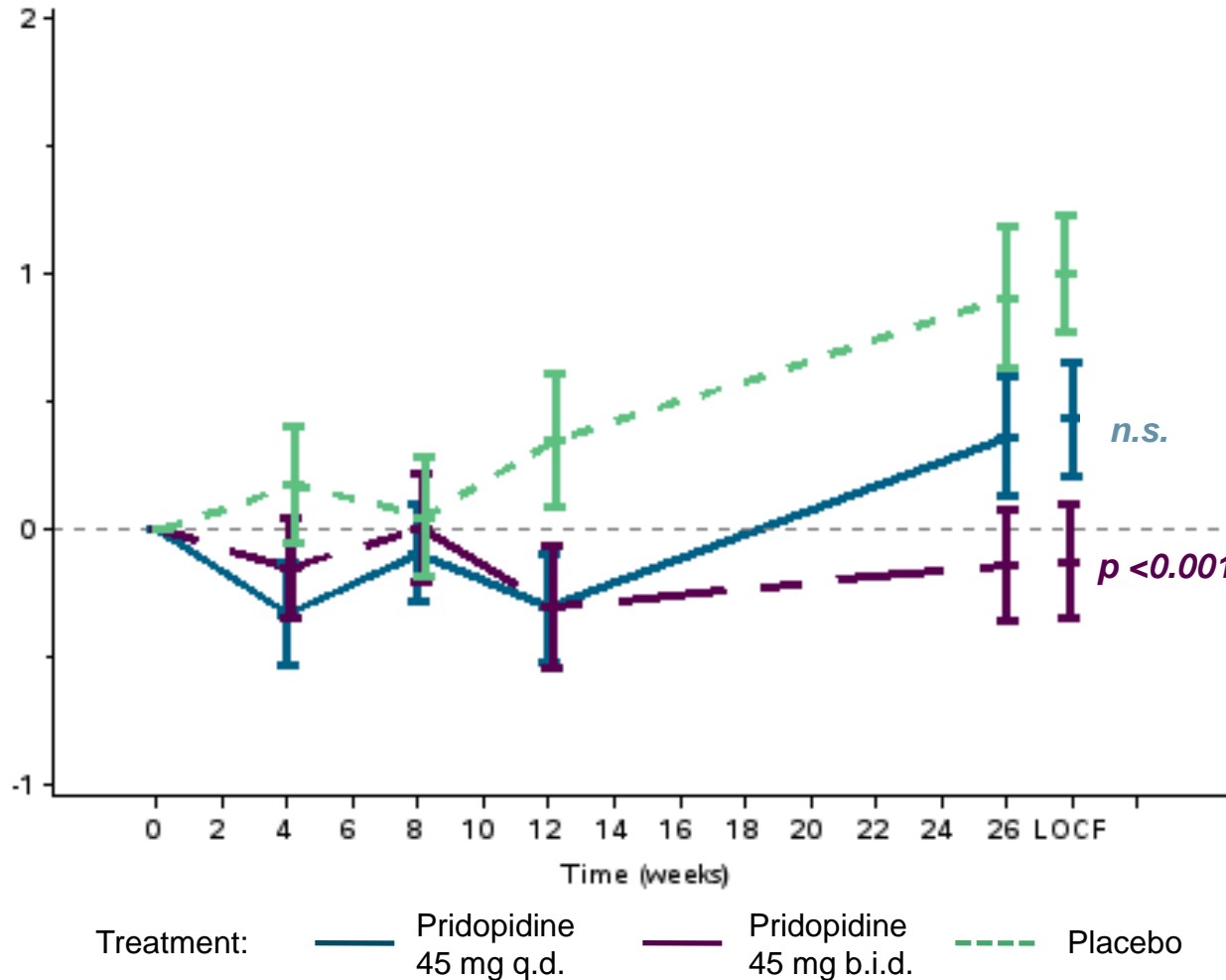
Full analysis set (ITT population)

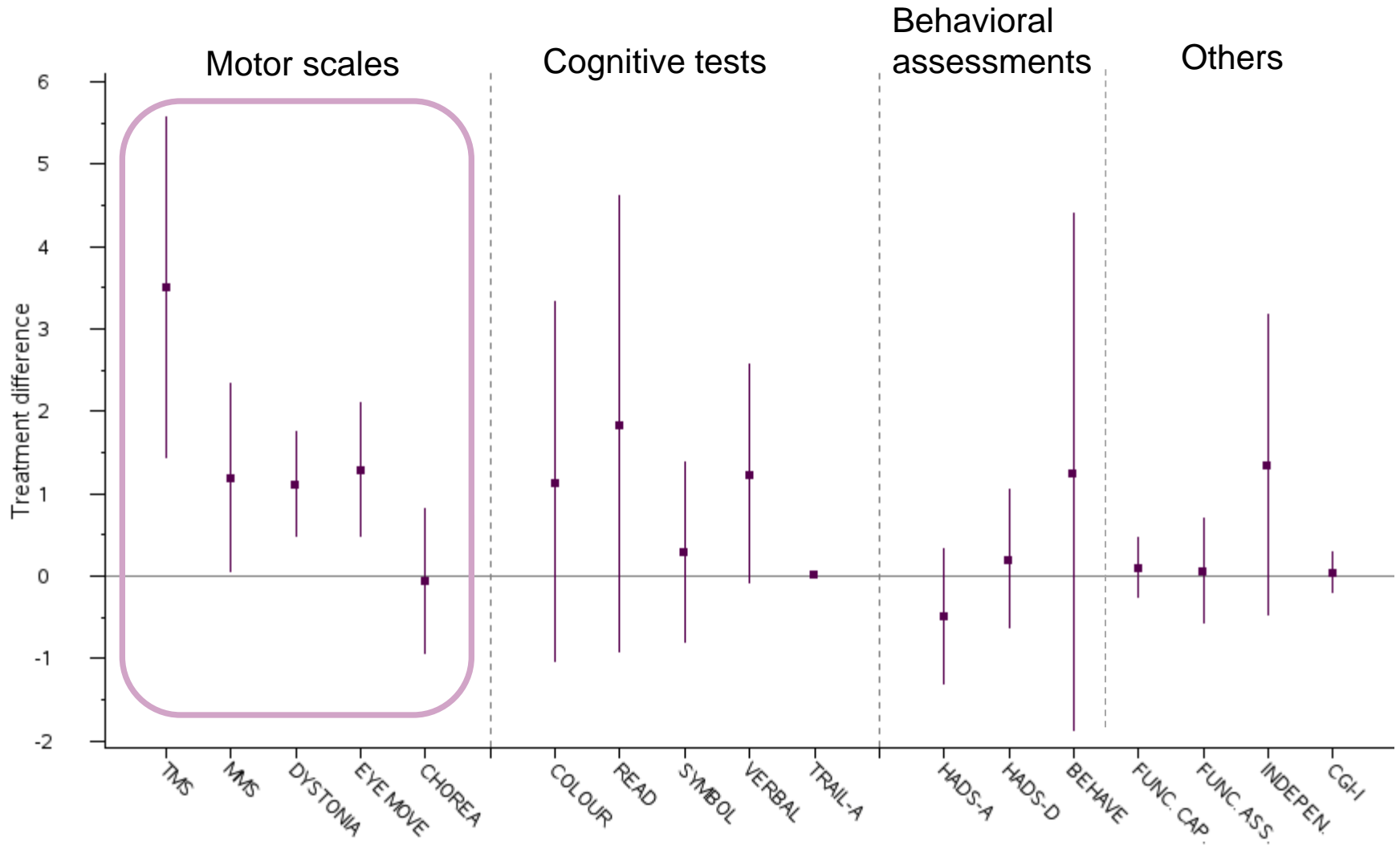


Significant improvement of Dystonia



Full analysis set (ITT population)





Huntexil[®] - Disease modifying properties and new IP



Results from the MermaiHD study show:

- In the placebo group, there is a highly statistically significant effect of CAG repeat length (CAGn) on symptoms progression;
i.e. the longer the CAGn the faster the natural progression
(confirms published findings from other studies, 2008-2009)
- In the Huntexil[®] treatment groups, the CAGn dependent deterioration is no longer there (highly significant interaction between CAGn and treatment),
i.e. treatment with Huntexil[®] removes the natural progression of disease symptoms
- Results also show that there is no significant interaction between baseline severity of motor disabilities and treatment,
i.e. treatment is equally effective independent of severity at study start

NeuroSearch has filed for new IP covering Disease modifying effects of Huntexil

Conclusions from the MermaiHD study



In the MermaiHD study, Huntexil[®] has demonstrated to

- Significantly improve motor functions
 - Significant effect on both voluntary and involuntary disease symptoms
 - Translating into an estimated ½ to 1½ years of symptoms progression set-back

- Have a very good safety and no disadvantages

- Potential disease modifying properties

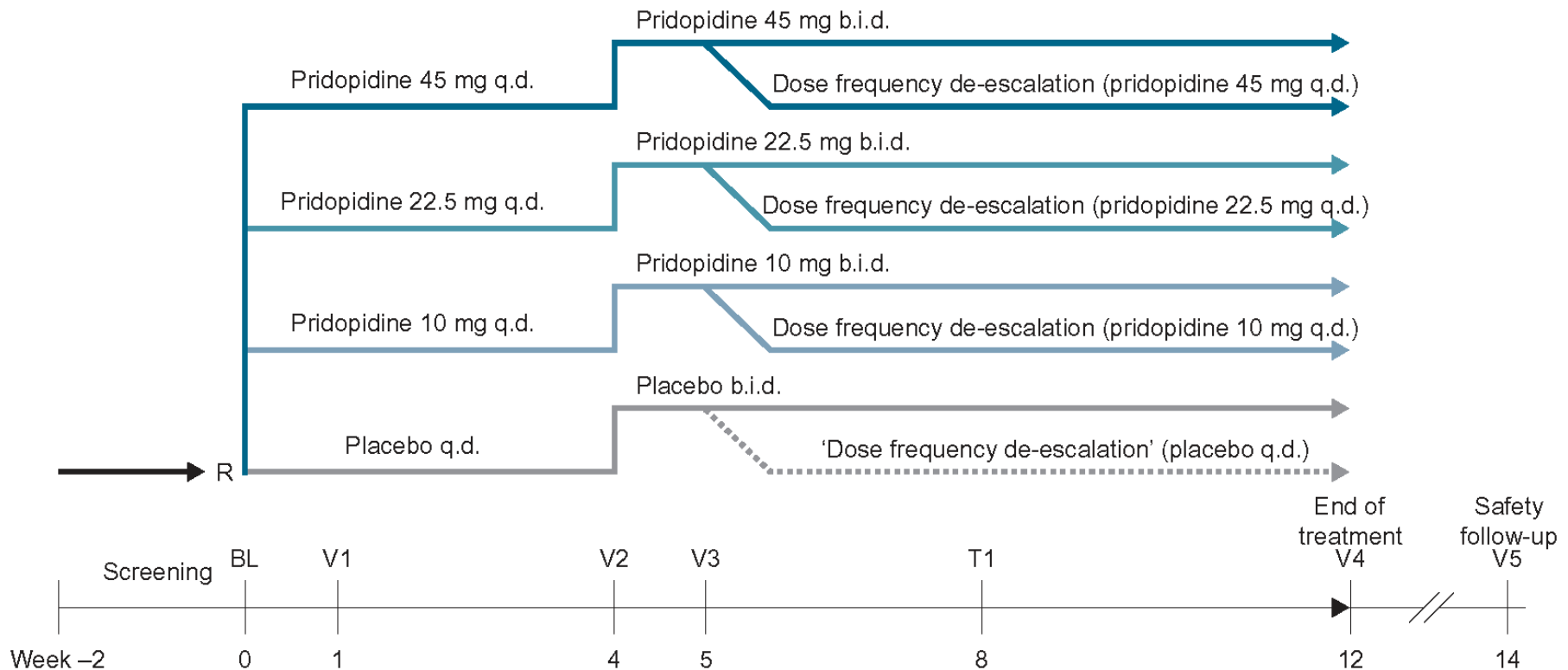
- Results confirmed in patients both on and not on neuroleptic treatment

- Further in-depth analysis of the results is ongoing

The HART study - Design



- A 12 week randomized, double-blinded, parallel-group study, comparing treatment with Huntexil® 45 mg once daily or twice daily versus placebo for the symptomatic treatment of HD



BL = baseline; b.i.d.,= twice daily; q.d. = once daily; R = randomization; V = visit; T = telephone contact.

Huntexil[®] - Commercial route



- Further results from the pivotal programme expected in H2 2010
 - Results from 12 weeks randomised study, the HART study in NA
 - Results from 26 weeks open-label extension to the MermaiHD study

- Other initiatives
 - Cost-of-illness study ongoing in major markets to support the overall benefit of Huntexil[®]
 - Planning for launch of Early Access Programme in both Europe and the US in 2010
 - Preparing for clinical publications of results from the MermaiHD study

- Planning for registration (MAA/NDA)
 - Based on the combined study results from the pivotal programme
 - Dialogue with regulatory authorities to be initiated based on the MermaiHD study results

Huntexil[®] – Aiming for market registration as fast as possible

Key products

Tesofensine

– Highly efficacious obesity drug candidate ready for Phase III

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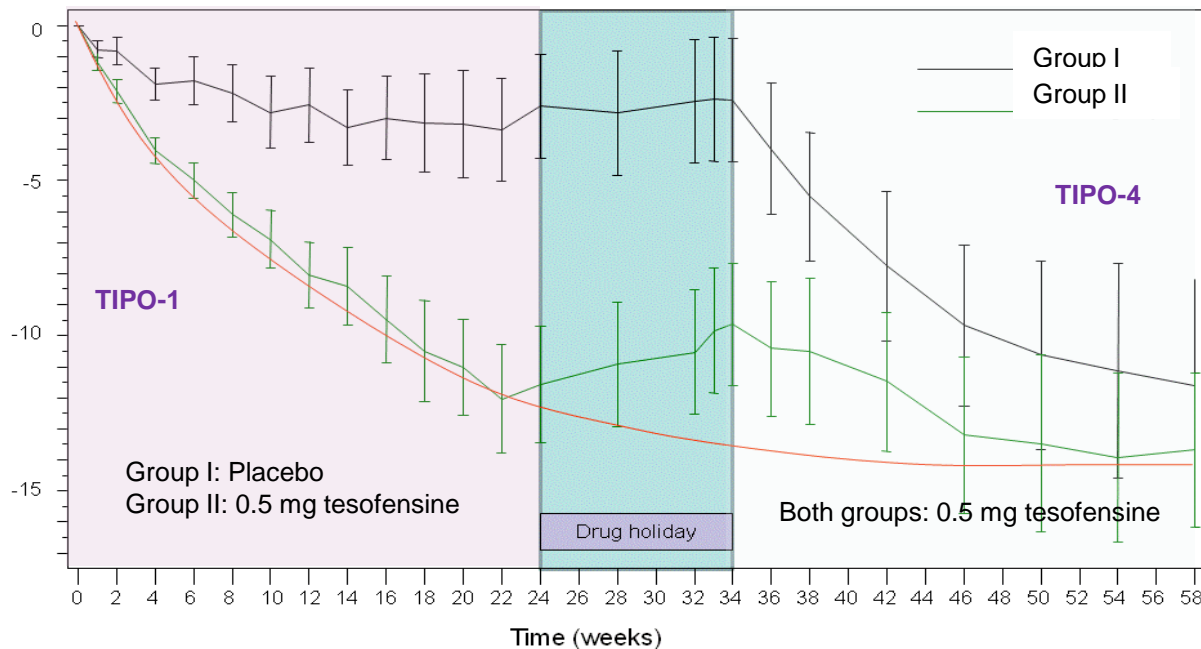
Tesofensine (obesity) - Long term weight loss



Combined weight loss from TIPO-1 (Phase II POC study) + TIPO-4 (extension study)

- Combined ~ 12 month (48 weeks) weight loss of 13-14 kg (sustained after 72 wks)
- Confirmed 6 month (24 weeks) placebo-adjusted weight loss of 9 - 10 kg

Weight loss
in kg vs baseline



- TIPO-1: Significant weight loss over first 24 wks in the tesofensine (0.5 mg) group compared to the placebo group
- During the 8 wks drug holiday the tesofensine group regained weight
- After the drug holiday, both groups receive tesofensine (0.5 mg), and a significant weight loss is observed in the former “placebo” group

Tesofensine has demonstrated strong long-term weight loss effect

Tesofensine – Developmental status and plans



End of Phase II meeting with the FDA

Major data package supporting tesofensine's attractive efficacy and safety profile

- PoC Phase II study (TIPO-1)
- Phase II extension study (48 weeks) (TIPO-4)
- Meta-analysis of Phase II efficacy/safety data in elderly patients (AD/PD)
- Confirmative human metabolic study (TIPO-2)
- Cardiovascular safety study
- Abuse liability study

➔ Endorsement and support from the FDA on Phase III programme

However,

following the results of the SCOUT trial and the subsequent withdrawal of sibutramin

NeuroSearch is evaluating the Phase III plan and the regulatory pathway, aiming for start of first Phase III study in 2010

Tesofensine has demonstrated a very attractive product profile and is ready for Phase III

Key products

ABT-894, ACR343 and ACR325 - Ready for Phase II

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ABT-894 (Abbott) – Progressing in ADHD



- **ABT-894 has shown positive results in a Phase II study in adult ADHD**
 - Demonstrated efficacy and good safety (compared to Strattera)
- **Abbott has been working to optimise the product and plans for a clinical Phase II study in children with ADHD**
- **Abbott finances and is responsible for the development and commercialisation of ABT-894**
- **NeuroSearch is eligible to milestones and royalties**

ADHD – About the market

- **An estimated 3-6% of pre-school and school age children has ADHD**
- **In 30-50% of paediatric ADHD cases, symptoms persist through adolescence and into adult age**
- **Today, only 10-15% of adults with ADHD receive treatment, compared to 80-90% for children**
- **Existing treatment only treats part of the disease symptoms and is associated with side-effects and risk of abuse**

Phase II candidates – ACR343 and ACR325



ACR343 and ACR325 are the next dopaminergic stabilisers in NeuroSearch's pipeline after Huntexil[®] - and with the following characteristics;

Stabilise dysregulated psychomotor functions through their primary action as fast-off kinetics at the dopamine D2 receptors, i.e.

- Have limited or no effects on normal behaviour
- Result in slight dopaminergic activation in hypoactive states
- Suppress hyperactive behaviour as induced by stimulants

Suited for clinical indications with hyper or hypo dopaminergic functioning – or both, such as:

- Huntington's disease (Huntexil[®]) – Phase III ongoing
- Parkinson's dyskinesias (ACR325) – Phase Ib in PD patients ongoing
- Schizophrenia as add-on (ACR343) – Phase II to be launched in H1 2010
- Other neurodegenerative disorders (defined specialist indications)

(Early clinical trials with Huntexil[®] have shown reassuring results in both HD, PD and schizophrenia)

Establishing a portfolio of specialty CNS drugs with unique therapeutic characteristics

Near term milestones

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2010 – Expected milestones



Huntexil® - Huntington's disease

- Potential initiation of Early Access Program
- Results from the HART study (confirmatory Phase IIb study in NA)
- Results from 6 months extension phase of the MermaiHD study (12 mths data)
- Regulatory process

Tesofensine - Obesity

- Final development and regulatory strategy established
- Initiation of Phase III
- Partnering

ACR343 - Schizophrenia

- Initiation of Phase II study in schizophrenia

ACR325 - Dyskinesias in Parkinson's disease

- Results from Phase IB study in Parkinson patients
- Initiation of Phase II study

Advancements in partner collaborations

- Abbott: Progression of development for ABT-894 in ADHD
- Progress in the drug discovery alliances



Appendix

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Cochrane chart on tetrabenzazine (TBZ)



UHDRS & FIS Assessments (baseline to aver. wks.9 + 12)	Endpoint	TBZ	Placebo	p-value ANCOVA
Total Motor Score	2 ^o	-6.84	-3.51	0.075 T
Total Chorea Score	1 ^o	-5.04	-1.52	<0.001 T
Gait Score	2 ^o	0.00	0.11	0.241 T
Cognition Score*	Exp.	-0.58	2.23	0.224 P
Behavioral Assessment (BA)	Exp.	-0.98	-2.22	0.363 P
Functional Assessment (FA)	2 ^o	-0.81	0.37	0.018 P
Independence Scale (IND)	Exp.	-1.98	0.55	0.135 P
Functional Capacity (TFC)*	Exp.	-0.43	-0.06	0.291 P
Functional Impact Scale (FIS)*		0.11	0.13	0.970



T = favors TBZ. P = favors Placebo. * = Wk. 12 data only

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Source: FDA homepage



For more information, please visit www.neurosearch.com or write
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