



Newron Pharmaceuticals S.p.A.

Media and analyst conference
Full year results 2008

Zurich

April 2, 2009

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Agenda



- Start 10:30 am CET
- Welcome Luca Benatti, CEO
- R&D pipeline update Luca Benatti, CEO
- Financial review and outlook Stefan Weber, CFO
- Q&A Audience present / conference call participants
- End 11:45 am CET
- Imbiss

Overview



- Focus on global CNS and pain markets, addressing diseases with significant unmet medical needs
- Late-stage validated clinical pipeline
- Proven drug discovery expertise
- Management with proven track record of bringing CNS drugs to market (Comtan™, Cabaser™, Exelon™, Clozaril™)
- Pipeline expanded through acquisition of neuro-inflammation company Hunter-Fleming, April 2008
- Operations in Bresso (I), Basel (CH) and Bristol (UK)
- Listed on main segment of SIX Swiss Exchange (NWRN)

Recent Milestones



- Safinamide significantly improved motor function in patients with advanced PD in Phase III Pivotal Trial
- EPO grants two new patents on safinamide significantly extending its use
- Exciting Phase II results with ralfinamide in Neuropathic Low Back Pain (NLBP)
- Start Phase IIb/III trial with Ralfinamide in NLBP
 - First patients randomized
 - EMEA approved NLBP indication, development plans, study design, outcome measures, diagnostic criteria and statistical analysis plan
- Acquisition and integration of Hunter-Fleming Ltd.
- Positive Phase II safety and tolerability results for HF-0220 in Alzheimer's disease
- EUR5m Italian government R&D grant
- CHF30m long term standby equity line

Broad and diversified pipeline



		Lead	Preclinical	Phase I	Phase II	Phase III
Safinamide ⁽¹⁾	Adjunctive to dopamine agonist Early Stage PD	[Progress bar spanning Lead, Preclinical, Phase I, Phase II, and Phase III]				
	Adjunctive to levodopa Mid to late Stage PD	[Progress bar spanning Lead, Preclinical, Phase I, Phase II, and Phase III]				
Ralfinamide	Neuropathic Low Back Pain	[Progress bar spanning Lead, Preclinical, Phase I, and Phase II]				
	Inflammatory Pain	[Progress bar spanning Lead, Preclinical, and Phase I]				
HF 0220	Alzheimer's disease	[Progress bar spanning Lead, Preclinical, Phase I, and Phase II]				
	Rheumatoid Arthritis	[Progress bar spanning Lead, Preclinical, and Phase I]				
HF 0420	Anti-cancer therapy induced neuropathy	[Progress bar spanning Lead, Preclinical, and Phase I]				
HF 0299	Neuropathic pain	[Progress bar spanning Lead, Preclinical, and Phase I]				
NW 3509	CNS-related disorders/pain	[Progress bar spanning Lead and Preclinical]				
HF 1220 Series	Neuroprotection	[Progress bar spanning Lead]				
IC ⁽²⁾	CNS-related disorders/pain	[Progress bar spanning Lead]				

(1) Newron is undertaking Phase III trials with safinamide for the treatment of PD on behalf of its partner Merck Serono

(2) IC = Ion Channel Program

(3) HF 1020 in preclinical development for asthma is part of Newron's equity holding in Trident



Safinamide

Once a day oral adjunctive therapy for any stage of PD

Parkinson's disease: a large and growing market



- A neurodegenerative disease with progressive deterioration of motor functions
- The most common serious movement disorder in the world
- It affects about 1% of the population over 60 years of age
- >\$4bn market with double digit growth since 2003

Safinamide



- Once a day oral adjunctive therapy for any stage of PD
- Unique mechanism of action
 - Enhancement of dopaminergic function
 - Reduction of glutamatergic activity
- Small molecule, high bioavailability
- Currently in Phase III development for PD with partner Merck Serono
- Potential in cognitive disorders
- New patents granted significantly extend protection in EU, under review in the US
 - Add-on to L-dopa patent
 - Use patent for RLS

Target Product Profile



Current PD paradigm

Early stage (mild)



Late stage

Dopamine agonist

- First-line treatment in early patients, efficacy decreases over time, significant side-effects

Levodopa + adjunct

- Associated with dyskinesia and other major side effects

Safinamide enhances existing treatment paradigm

Early stage (mild)



Late stage

Dopamine agonist

Dopamine agonist + safinamide

- Enhances dopamine agonist effects
- Delays levodopa use
- Improves cognition

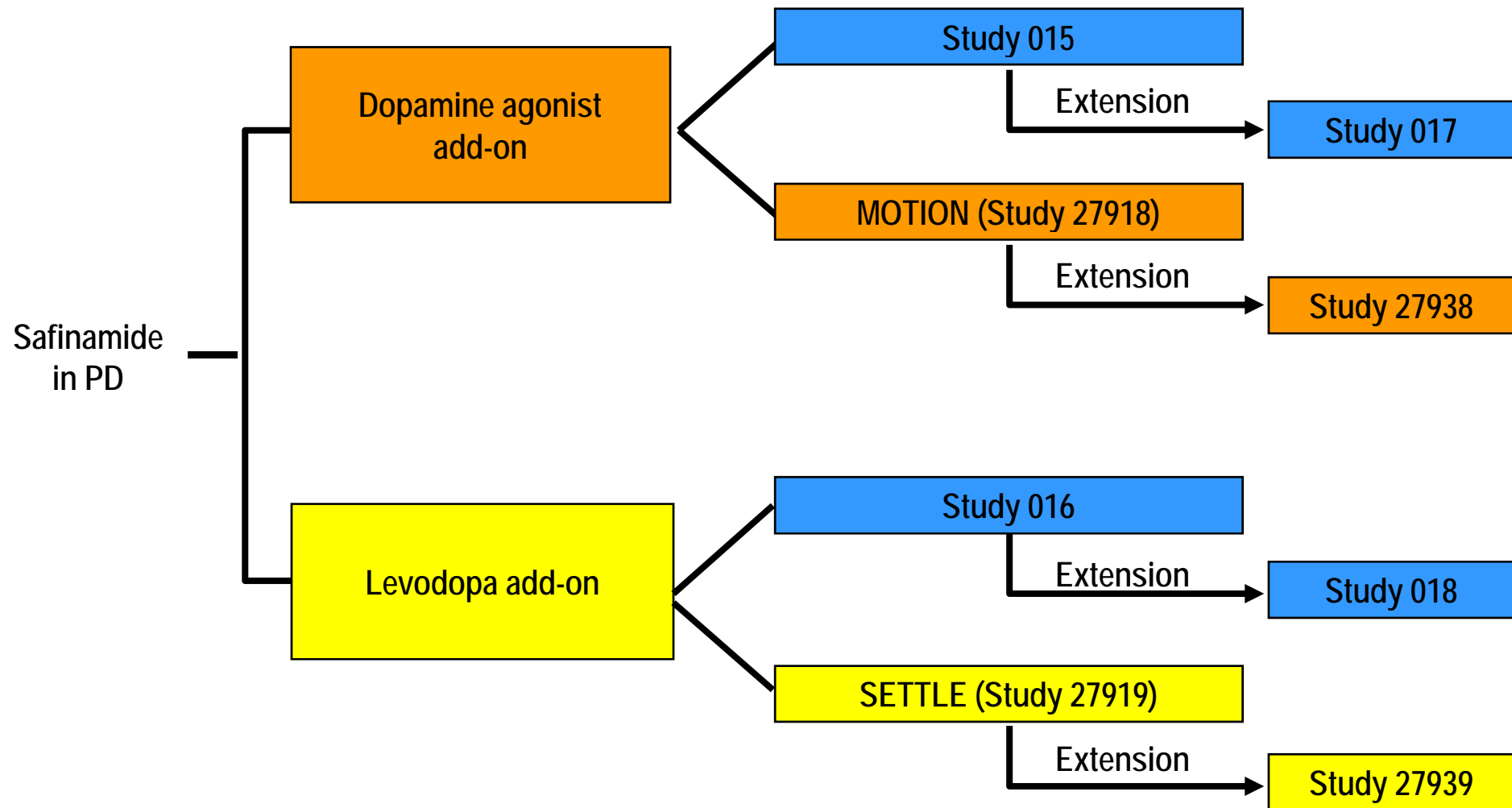
Levodopa + (adjunct +) safinamide

- Improves "on" time, reduces "off" time
- Improves dyskinesias *
- Reduces levodopa dose *
- Improves cognition *

* as suggested by earlier studies and mechanism of action

**Delay the use of levodopa as long as possible;
once you use levodopa, dose as low as possible**

Safinamide Clinical Development Plan



Add-on to Dopamine agonists in early PD



- Phase II placebo-controlled study in early PD patients on DA:
 - Statistically significant and clinically relevant superiority at a daily dose of 1 mg/kg (~85 mg) of safinamide on motor symptoms (UPDRS III)
- First phase III trial confirmed positive phase II results:
 - Safinamide 50 to 100mg/day added to patients who are still benefiting from DA treatment showed:
 - at 6 months
 - Statistically significant, clinically relevant improvement in motor symptoms (UPDRS III)
 - Statistically significant improvement in activities of daily living (UPDRS II) and quality of life (EUROQOL)
 - Statistically significant improvement on two cognitive domains impaired in early PD (executive functioning and working memory)
 - at 18 months
 - Side effects reported with similar frequency in patients receiving safinamide and in placebo group
 - Statistically significant improvement in motor symptoms (UPDRS III) and quality of life (EUROQOL)
 - Potential to reduce the number of patients experiencing interventions

Add-on to L-dopa in mid-to-late stage PD Study 016 – Design



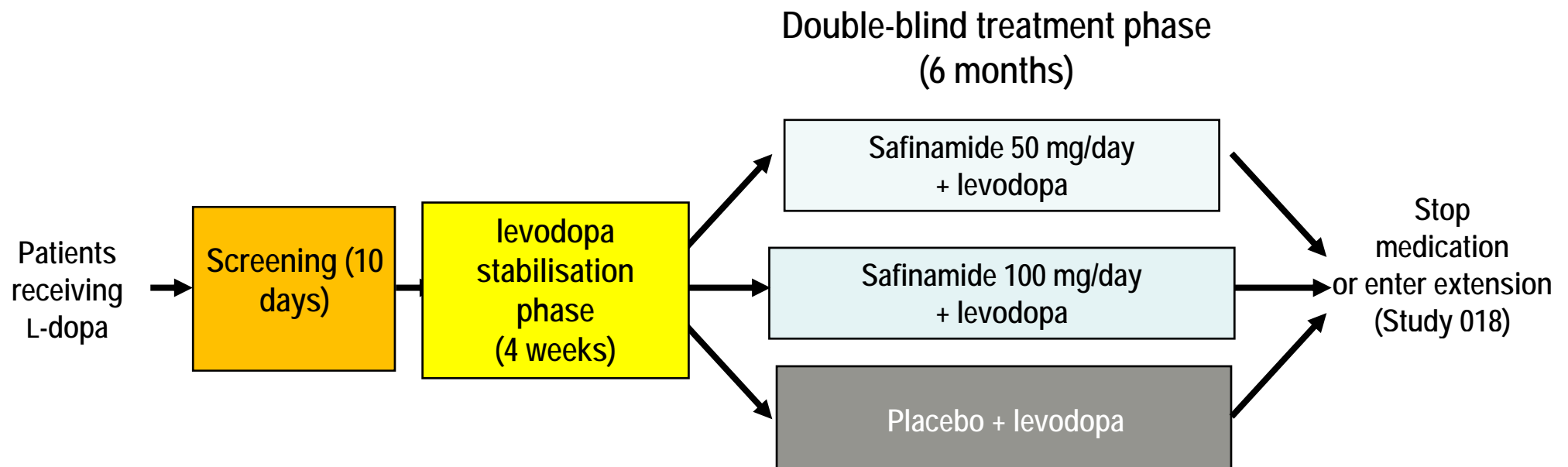
- Double-blind, placebo-controlled, parallel-group, randomised, multi-centre multi-national, Phase III trial
- Comparing **two doses of safinamide (50 and 100 mg/day, p.o.) versus placebo**
- **Once per day** administration in the morning
- **669 subjects** randomized across 55 sites in Europe and Asia
- Eligible patients will be treated for a total of 2 years
 - This will be achieved by the patients participating in the two protocols:
 - **Study 016: duration of treatment is 24 weeks**
 - Study 018: duration of treatment is 18 months
- Data from the first 6 months of treatment being analyzed separately, and the **blind will be maintained throughout the additional 18 months of treatment**

Add-on to levodopa in mid-to-late stage PD

Study 016 – Objectives/Design



To evaluate the efficacy and safety of safinamide 50 and 100 mg/day, compared to placebo, in patients with PD with motor fluctuations and currently receiving an 'optimized' PD treatment with levodopa (incl. **COMT inhibitors and Stalevo**) and other PD therapies (**dopamine agonists, anticholinergics, amantadine**)



Add-on to L-dopa in mid-to-late stage PD

Study 016 – Efficacy variables



- **Primary efficacy variable**

Increase in mean daily “ON” time (“ON” time without dyskinesia plus “ON” time with minor dyskinesia)

- **Secondary efficacy variables analyzed to date**

- Decrease in total daily “OFF” time
- Decrease in mean “OFF” time following first morning dose of levodopa
- UPDRS Section III during “on” phase
- CGI - Severity of illness
- CGI - Change from baseline

Full study results (incl. further secondary and tertiary endpoints) will be submitted for presentation at upcoming scientific meetings after completion of ongoing analyses

Add-on to L-dopa in mid-to-late stage PD

Study 016 – Inclusion criteria



Patients met the following criteria:

- Male or female, aged 30-80 years
- **Diagnosis of idiopathic PD of > 3 yrs**, based on medical history and neurological examination
- Hoehn and Yahr stage of I-IV during an “OFF” phase
- **Levodopa responsive** and receiving a stable dose of levodopa at screening
 - **4-10 doses per day**
 - Any levodopa preparation (CR, IR or CR/IR combination) plus benserazide/carbidopa
 - COMT inhibitors permitted (including Stalevo®)
- Patients may be receiving **concomitant treatment with stable doses of a dopamine agonist and/or an anticholinergic**
- Motor fluctuations with >1.5 hrs “OFF” time during day
- **Ability to maintain diary (18-hr) with help of caregiver**
- Willing and able to provide informed consent in writing

Add-on to L-dopa in mid-to-late stage PD

Study 016 – Efficacy endpoints

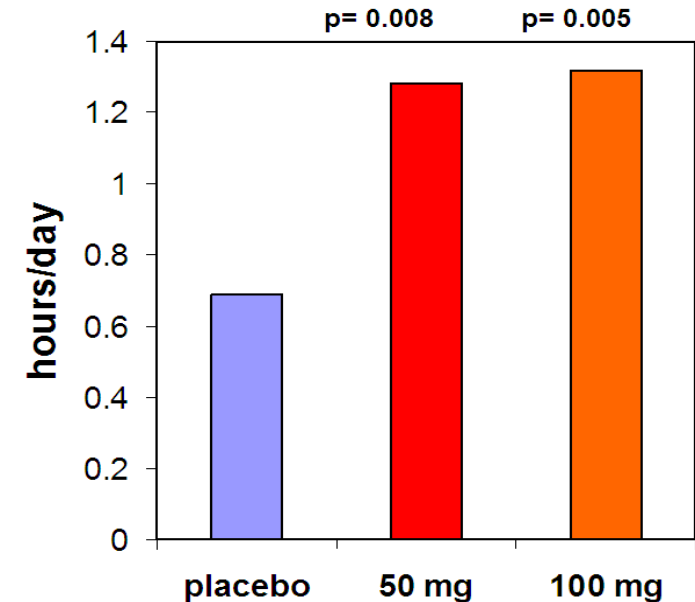


Primary endpoint met

Total Daily “ON” Time
- Average increase vs baseline

Secondary efficacy endpoints analyzed to date also met
(statistically significant improvement compared to placebo)

- Total Daily “OFF” Time
- OFF Time After Morning Dose of Levodopa
- UPDRS Part III (motor) “ON”
- Clinical Global Impression – Severity
- Clinical Global Impression – Change



Full study results will be submitted for presentation at upcoming scientific meetings after completion of ongoing analyses

Add-on to L-dopa in mid-to-late stage PD

Study 016 – Safety



- High completion rate
 - 89% of patients treated with safinamide completed the study
 - 91% in the 50 mg dose group
 - 87% in the 100 mg dose group
 - 89% of patients who received placebo completed the study
- Incidence of dropouts, serious adverse events or clinically notable events comparable among the three groups of the study

Add-on to L-dopa in mid-to-late stage PD Study 016 – Topline results - Conclusions



- First Phase III study of safinamide as add-on to levodopa demonstrates statistically significant and clinically relevant efficacy of both 50 mg/day and 100 mg/day of safinamide
 - **Primary efficacy endpoint met:** safinamide significantly improved motor symptoms by increasing “ON” time
 - **Secondary efficacy endpoints analyzed to date met:**
 - Decrease in daily “OFF” time
 - Decrease in mean “OFF” time following first morning dose of levodopa
 - Mean change from baseline UPDRS Section III (motor) score during “ON” time
 - Mean change in Clinical Global Impression of severity of disease
 - Change in Clinical Global Impression from baseline
- **Study had high completion rate (approx 89%)**
 - Incidence of dropouts, serious adverse events or clinically notable events comparable among the three groups of the study
 - High rate (over 90%) of roll-over into extension study
- Full study results will be submitted for presentation at upcoming scientific meetings
- Newron & Merck Serono are completing the development program towards the registration of safinamide in PD (MOTION ongoing/SETTLE to be started within short)



Ralfinamide

First in-class agent for the treatment of NLBP

Ralfinamide: an innovative therapeutic agent for Neuropathic Low Back Pain



- Oral use, small molecule, new chemical class
- Modulation of Na, Ca, NMDA receptors: key targets for the control of pain transmission
- Most potent inhibitor of Na(v)1.7 channel in clinical development
- Long-lasting anti-allodynic and anti-hyperalgesic effects in models of neuropathic and inflammatory pain
- No development of tolerance on chronic dosing
- No need for titration
- Demonstrated efficacy in placebo-controlled trial in patients with peripheral neuropathic pain
- First in-class agent for the treatment of NLBP

Neuropathic Low Back Pain



- 55 million patients estimated
- Restricted activity and quality of life
- Often chronic and debilitating
- No drugs have received regulatory approval for this indication yet
- Market opportunity confirmed by prescriptions vs other NP
 - ~ 85m TRxs for NLBP vs 15-20m TRxs for PDN/PHN

Phase II in Neuropathic Pain



- Multi-centre, randomised, D-B, placebo-controlled, flexible ascending dose (80-320mg/day) study
- 272 patients with **mixed neuropathic pain syndromes**, including diabetic neuropathy, post-herpetic neuralgia, nerve compression and entrapment (NCET)
- Treatment duration: 8 weeks
- Clear evidence of efficacy with positive effect seen both as change vs baseline as well as proportion of patients with at least 50% improvement on:
 - VAS
 - Likert (Pain)
 - Daily Diary Sleep
 - Daily Diary Activity
- Ralfinamide was well tolerated with no evidence of any statistically significant or clinically relevant pattern of change compared to placebo

Responder analysis: proportion of patients with a VAS decrease of at least 30% or 50% - NCET



VAS Responder rate LOCF	Nerve Compression/Entrapment - ITT			
	30%		50%	
Treatment	Ralfinamide	Placebo	Ralfinamide	Placebo
N	57	39	57	39
Proportion of responders n (%)	31 (54.4)	13 (33.3)	26 (45.6)	8 (20.5)
Odds ratio	2.38		3.25	
95% CI for odds ratio	1.02, 5.55		1.27, 8.29	
P-Value (A)	0.043 *		0.012 *	

Responder analysis: Likert pain (proportion of patients with a decrease of at least 30% or 50%) – NCET



Responder rate LOCF	Nerve Compression/Entrapment - ITT			
	30%		50%	
Treatment	Ralfinamide	Placebo	Ralfinamide	Placebo
N	57	39	57	39
Proportion of Responders n (%)	33 (57.89)	14 (35.90)	24 (42.11)	7 (17.95)
Risk Difference (95% CIs)	22.0 (2.2, 41.8)		24.2 (6.6, 41.7)	
Chi-Square P-value (A)	0.0342 *		0.0129 *	

Responder analysis: Likert pain (patients with 2 or more point improvement) - NCET



Responder rate LOCF	Nerve Compression/Entrapment	
	Ralfinamide	Placebo
Treatment		
N	57	39
Proportion of Responders n (%)	31 (54.4)	11 (28.2)
Odds Ratio (95% CI for Odds Ratio)	3.03 (1.27, 7.25)	
P-value (A)	0.012 *	

Comparability of response to Ralfinamide in patients diagnosed with NCET vs NLBP



50% Responder rate LOCF	NCET – ITT		NLBP - ITT	
	RALF	PBO	RALF	PBO
Treatment				
N	57	39	33	21
Proportion of responders n (%)	26 (45.6)	8 (20.5)	11 (33.33)	2 (9.52)
Difference	25.1		23.8	
P-Value	0.012 *		0.0460 *	

Phase IIb/III in NLBP: Study Design



- Double-blind placebo controlled, parallel-group, multinational trial
- Treatments:
 - Placebo and 2 doses of ralfinamide (**160mg and 320 mg daily**)
- Randomisation: Equally to all three groups
- Study Duration: **12 weeks**
 - Patients who complete 12 weeks of treatment will be eligible to enter a double-blind 40 week extension
 - Patients will continue on the same dose of study medication they were receiving at the end of the 12 week treatment period
- Number of Patients: **approx 400**

Phase IIb/III in NLBP: Diagnostic Criteria



- **At least moderate (>40mm) pain** as judged by patients' self ratings on the VAS
- Present for at least 3 months but not longer than 3 years
- Diagnostic criteria as specified in the Int. Ass. for the Study of Pain (IASP) Classification of Chronic Pain
- **Pain is due to a lesion of the PNS**
- Neuropathic nature of the low back pain is confirmed by
 - **A score >18 on the Pain Detect Questionnaire**
 - **Cutaneous and sensory testing** confirms the involvement of dermatomes corresponding to L1-S1
- Test of muscle power, flexion, and reflexes support the diagnosis
- Imaging will be performed where necessary to confirm the diagnosis

Phase IIb/III in NLBP: Clinical



- Primary Efficacy Measure
 - Mean percent on 11-point Likert Scale measuring intensity of pain
- Key Secondary Measures
 - Mean percent change on the VAS (100mm line) measuring intensity of pain
 - Responder rate (30% and 50%) improvement on the Likert/VAS
- Safety Measures
 - ECG, Laboratory, Vital signs etc.

Phase IIb/III in NLBP: Status



- First patient randomized on March 31, 2009
- EMEA approved:
 - Plans for the NLBP indications
 - Study design
 - Diagnostic criteria
 - Outcome measures
 - Statistical analysis
- EMEA agreement confirms the earlier consensus by a number of Health Authorities in North America and Europe
- Top line results 1H2010

Ralfinamide in NLBP



- NLPB is a large market
- Area of high unmet patient need
- No approved medications
- Favorable access and pricing
- Physicians agree most Chronic Back Pain has a neuropathic component
- Opportunity to transition from NLBP to Chronic Back Pain (CBP)
- Ralfinamide may become the first approved drug for NLBP
- Blockbuster potential



HF0220

Potential first-in-class neuroprotective agent

HF0220: the concept



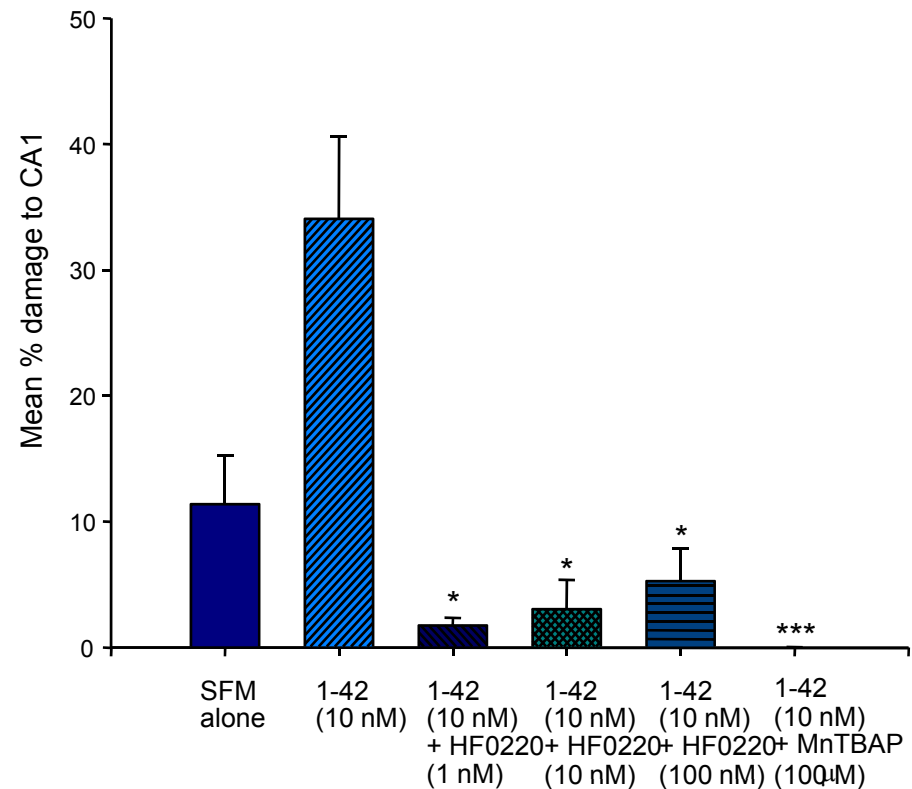
- HF0220 is the 7- β -hydroxyl derivative of epiandrosterone (EPIA)
- EPIA and the related dehydroxy-EPIA (DHEA), are **naturally occurring neuroprotectant** steroids whose formation is increased in response to oxidative stress. Their activities are mainly due to their 7-hydroxyl derivatives
- Hydroxylation to 7- α is mediated by CYP7b and further conversion to 7 β -hydroxyl derivatives by 11 β -HSD1
- This **conversion is impaired in pathological conditions**, such as AD
- The administration of HF0220 may overcome this deficit in neurodegenerative diseases

HF0220 has potential to be first-in class neuroprotective agent



Significant protective effects on β -amiloid- and serum deprivation-induced neurotoxicity in organotypic hippocampal slices

- HF0220 showed strong neuroprotective effects in several experimental models of neurotoxicity, both in vivo and in vitro
- A potential “first-in-class disease-modifying agent” for neurodegenerative diseases



HF0220 showed safety and tolerability in AD patients



- Multicenter, randomized, double-blind, placebo controlled pilot study in 42 patients with mild to moderate Alzheimer's disease
- HF0220 administered at doses ranging from 1 to 220 mg/day
- Patients allowed to continue current AD medication
- **Results:**
 - Drug was well tolerated, no difference to placebo
 - High rate of completion
 - Drug can be safely administered to AD patients with concomitant illnesses, more susceptible to side effects of existing medications



NW-3509

For the treatment of psychiatric disorders

NW-3509: addressing unmet medical needs in schizophrenia and bipolar disorder

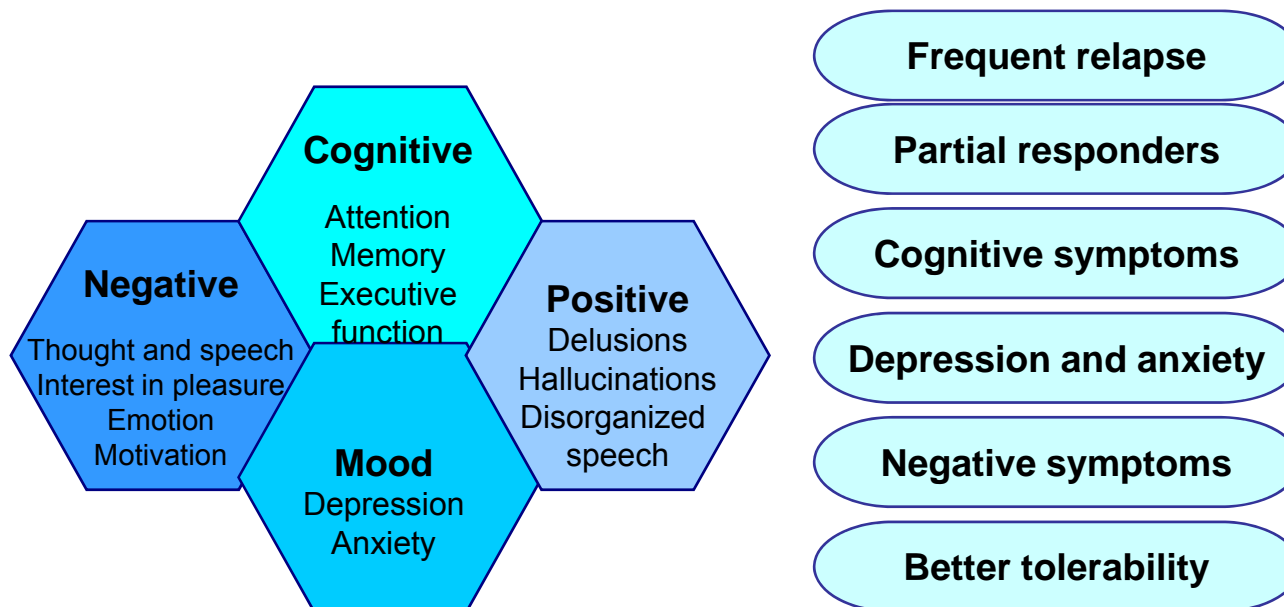


- Innovative compound from Newron's ion channel program
- Modulates neuronal systems involved in psychiatric disorders
- Fast onset of action with high availability in the brain
- NW-3509 has the potential to address unmet medical needs in schizophrenia and in bipolar disorder
- NCE patent filed in 2007
- Undergoing IND – enabling studies

Schizophrenia



- Antipsychotic market 2008 > \$ 22Bn
- Schizophrenia is characterized by **positive symptoms** (delusions, hallucinations), **negative symptoms** (poverty of speech, lack of spontaneity) and by a **profound disruption in cognition**.
- Schizophrenia shows a high rate of **co-morbidity**, including anxiety and depression
- Several major needs remain unmet by current medications, such as cognitive impairment, incomplete/partial responders and co-morbidities



NW-3509 has the potential to address unmet medical needs in schizophrenia



- **Cognitive symptoms**
 - NW-3509 is active in models of short and long-term memory impairment. Most antipsychotic have detrimental effect on cognition
- **Incomplete/partial responder patients**
 - NW-3509 is active in models of information processing, elicited by different mechanisms, both natural and pharmacological
- **Co-morbidities**
 - NW-3509 is active in models of anxiety and depression, suggesting to be able to address important co-morbidities in schizophrenia

NW-3509 has also potential in bipolar disorder



- Bipolar disorder is a complex disorder characterised by oscillation between periods of mania and depression. Bipolar depression is an important unmet medical need
- NW-3509 is active in a **mania hyperactivity model**, showing its potential on the manic phase of the disorder, without inducing sedation
- NW-3509 is active in a **model of depression**, suggesting a possible effect in the depressive phase of bipolar disorder



Financials

Financial Highlights 2008



- First time consolidation of subsidiaries in CH and UK
- License income EUR2.6m (2007: EUR4.0m) - revenue recognition from MS downpayment
- Other income EUR1.3m (2007: EUR0.1m) - grants, tax credits I, UK
- Gross R&D expenses €22.4m (2007: €18.0m), including safinamide-related expense
- Net R&D expenses €12.9m (2007: €8.5m), net of MS reimbursement of safinamide
- SG&A expenses €9.4 m (2007: EUR9.3m), including €1.3m one-time effect of HF post acquisition restructuring
- Financial income €2.0m (2007: EUR2.6m)
- Net loss €16.4m (2007: EUR11.1m)
- Net cash used in operating activities EUR19.9m (2007: EUR13.9m)
- Net decrease in cash and cash equivalents EUR21.9m (2007:11.6m)
- Cash position at year end 2008: EUR41.3m, plus option to CHF30.0m under equity line
- Net cash used in operating activities – guidance 2009: EUR25.0m

Solid cash position – R&D relief by Merck Serono

Financial Statements 2008 (IFRS)



Consolidated Income statement

EUR ('000)	2008	2007
License income	2,635	4,024
Other income	1,298	70
R&D expenses	(12,881)	(8,474)
Marketing and advertising expenses	(115)	(131)
General and administrative expenses	(9,256)	(9,170)
Operating Loss	(18,319)	(13,681)
Financial income, net	1,963	2,593
Income tax expense	(8)	(1)
Net loss	(16,364)	(11,089)
Loss per share in €	(2.74)	(1.90)

Consolidated Cash flow statement

EUR ('000)	2008	2007
Net cash used in operating activities	(19,932)	(13,866)
Net cash flows from investing activities	(1,615)	2,243
Net cash flows from financing activities	(343)	15
Net decrease in cash and cash equivalents	(21,890)	(11,608)

Consolidated Balance sheet

EUR ('000)	31/12/2008	31/12/2007
Non-current assets	13,303	852
Current assets	47,237	69,516
Total assets	60,540	70,368
Borrowings/Deferred tax liability - non-current	4,038	561
Deferred income - non-current	0	1,973
Employee severance indemnity/cash settled share-based liabilities	684	661
Current liabilities	10,007	9,773
Total shareholders' equity	45,811	57,400
Total equity and liabilities	60,540	70,368

Newron share information (SIX: NWRN)



- Number of shares
 - Fully paid in: 6,037,556 March 30, 09 (2007: 5,834,766)
(185,742 shares for HF in May 08)
(16,242 shares for YG in Jan 09)
 - Fully diluted (SOP): 6,347,561 March 30, 09 (2007: 6,137,451)
- Market capitalisation 31/3/2009:
 - Non-diluted: 105.1m CHF
 - Fully diluted: 110.4m CHF
- Analysts:
 - Karl Bradshaw, Morgan Stanley
 - Peter Welford, Jefferies
 - Andrew Weiss, Bank Vontobel
 - Carri Duncan, Sal. Oppenheim
 - Florian Gaiser, Kepler Equities
 - Olav Zilian, Helvea
 - Bob Pooler, Bank am Bellevue
 - S. Fazeli, M. Aitkenhead, Piper Jaffray

Anticipated 12 month milestones



- Start and completion of additional trials to allow regulatory filing of safinamide in PD
- Safinamide in mid-to-late stage PD: presentation of full study results at next scientific meetings
- IND for NW-3509
- Start of PoC trial of HF0220 as neuroprotectant
- Phase IIb/III results of ralfinamide in NLBP
- Ralfinamide partnership

Summary Highlights



- Leading the field in the development of novel therapies for the treatment of CNS and pain
- Late stage validated pipeline addressing major therapeutic indications
- Broad, expanded pipeline:
 - Safinamide: once a day oral adjunctive therapy for any stage of PD
 - Ralfinamide: potential first in-class therapy for NLBP
 - Highly promising earlier pipeline
- Goal is to become a Fully Integrated Biopharmaceutical Company