Newron Pharmaceuticals S.p.A.

Conference Call

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Agenda

- Company overview
- Ralfinamide results in peripheral neuropathic pain
- Nerve compression and entrapment market
- Ralfinamide results in post-surgical (dental) pain
- Summary

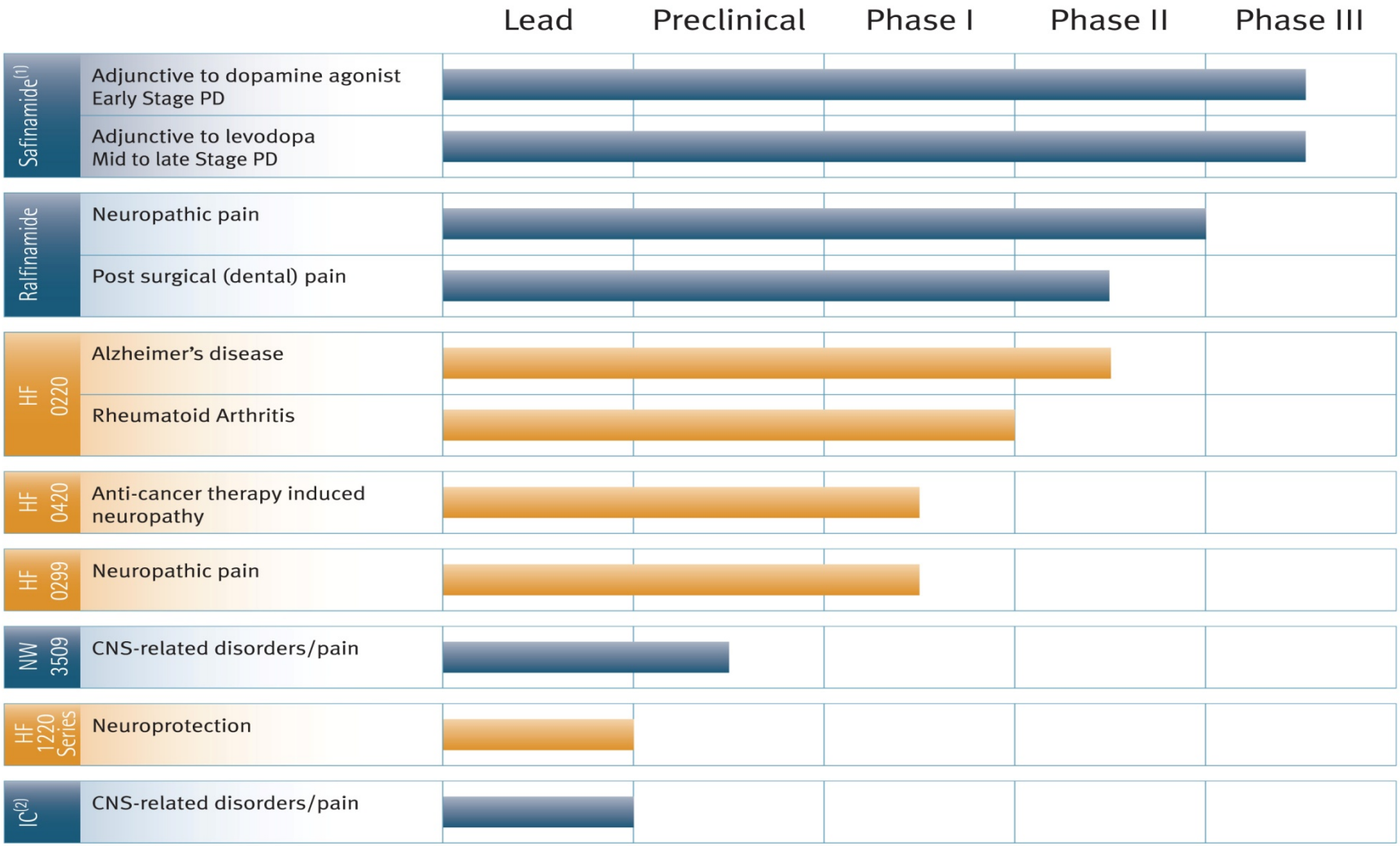
Overview

- Focus on global, growing CNS market, 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™)
- Total funds raised: € 137M
- Listed on main segment of SWX Swiss Exchange (NWRN)
- Strong analyst coverage
- Pipeline expanded through acquisition of neuro-inflammation company Hunter Fleming

Recent Milestones

- **Commercial settlement with Purdue – option to Purdue patents** √
- **Positive ralfinamide Phase II data in neuropathic pain** √
- IND approved for Ralfinamide in neuropathic pain √
- Start/completion of enrolment of ralfinamide Phase II study in post surgical (dental) pain √
- EU use patent for ralfinamide in migraine √
- **Positive safinamide 18 months Phase III data in PD** √
- **Start of safinamide Phase III MOTION trial (Merck Serono)** √
- **Extension of safinamide patent protection: EPO intention-to-grant letter** √
- **Start of development of NW-3509** √
- Opening of clinical development facility in Basel √
- Carlos de Sousa appointed as CBO √
- Dr. Hans-Joachim Lohrisch appointed non-executive member of BoD √
- **Acquisition of Hunter Fleming** √

Post Acquisition of Hunter-Fleming: CNS focus maintained, pipeline broadened



(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

Ralfinamide
Results in peripheral NP

Ralfinamide - an innovative therapeutic agent for neuropathic and inflammatory pain

- Oral use, small molecule, new chemical class
- Linear kinetics, excellent “drugability”
- Blocks ion channel subtypes, incl. Nav 1.7
- Long-lasting anti-allodynic and anti-hyperalgesic effects in models of neuropathic pain
- No development of tolerance on chronic dosing
- No need of titration
- One of the largest pharmaceutical market: analgesics ~23b$

MTD study 001
Key results

Ralfinamide MTD Study 001

- A phase II,
  - multicenter,
  - pilot,
  - randomized,
  - ascending dose,
  - double-blind,
  - placebo-controlled,
  - dose titration study to determine
    - safety,
    - maximum tolerated dose and
    - preliminary evidence of efficacy of ralfinamide in the range of 80-320 mg/day in patients with neuropathic pain

Study design

- Indication: Mixed Neuropathic Pain Syndromes
- Randomization: Unequal; ralfinamide vs placebo 2:1
- 272 patients
- Treatment duration: 8 weeks
- Countries: Austria; India; Italy; Poland; Czech-R; UK
- Primary efficacy measure: VAS score

Patient and analysis population

	Ralfinamide (n=177) 80-320 mg/day		Placebo (n=95)	
	N	%	N	%
Total randomized	177		95	
ITT Set All Patients randomised with at least one post-baseline efficacy value.	172	97.2%	95	100%
Modified Population (MPOP) All Patients randomised after study re-start.	129	72.9%	77	75.7%

Demographic data and types of Neuropathic Pain (NP)

	Ralfinamide	Placebo
Age in years: mean (SD)	58.1 (11.43)	56.7 (9.76)
Gender (male): number (%)	94 (53.4)	52 (54.7)
Body weight in kg: mean (SD)	75.6 (14.76)	76.5 (15.8)
Race number (%)		
• Caucasian	140 (79.5)	73 (76.8)
• Asian	36 (20.5)	21 (22.1)
PNP Diagnosis		
• NCET	59 (33.4%)	38 (41.1%)
• Diabetic neuropathy	44 (24.9%)	21 (22.1%)
• Ischemic nerve disease	10 (5.6%)	5 (5.3%)
• Traumatic neuropathy	27 (15.2%)	10 (10.6%)
• PHN	13 (7.3%)	7 (7.4%)
• Other	24 (13.6%)	13 (13.7%)

NCET: Nerve Compression or Entrapment

Study Disposition

Screened	**n=386**	
Treatment Groups	**Ralfinamide (n=177)**	**Placebo (n=95)**
Premature Termination	N= 56 (31.8%)	N= 22 (23.2%)
• Sponsor action[1]	16 (9%)	5 (5.3%)
• Protocol deviation	7 (4%)	3 (3.2%
• Lack of efficacy	4 (2.3%)	1 (1.1%)
• Consent withdrawn	14 (7.9%)	5 (5.3%)
• Loss to follow up/other	3 (1.7%)	3 (3.2%)
• SAEs	1 (0.6%)	1 (1.1%)
• Due to AEs (not rated serious)	11 (6.2%)	4 (4.2%)

[1]= treatment was terminated in these patients by the sponsor due to toxicology finding; study was reinitiated later after resolution of the issue

Most Frequent Adverse Events (≥5%)

Adverse Events (Preferred Terms)	Ralfinamide (n= 177)	Placebo (n= 95)
Headache	13 (7.3%)	10 (10.5%)
Nausea	9 (5.1%)	10 (10.5%)
Dyspepsia	5 (2.8%)	7 (7.4%)
Abdominal Pain	8 (4.5%)	5 [1 SAE] (5.3%)
CPK increase	4 (2.3%)	5 (5.3%)
Dizziness	6 (3.4%)	8 (8.4%)
Pruritus	3 (1.7)	5 (5.3%)
Retinal disorder	4 (2.3%)	5 (5.3%)
Vomiting	5 (2.8%)	5 (5.3%)

Results of Ocular Examination

Change from Baseline to Endpoint	Ralfinamide[1]	Placebo[1]
Patients with 1 New Abnormality	13 (11.5%)	7 (10.4%)
• Visual acuity	1 (0.9%)	0
• Visual fields left eye	10 (9.1%)	2 (3%)
• Visual fields right eye	7 (6.4%)	4 (6.1%)
• Fundoscopy left eye	1 (0.9%)	2 (3%)
• Fundoscopy right eye	0	2 (3%)

[1]= 113 patients in the ralfinamide and 67 in the placebo group underwent ocular examination

Differences in the Mean Change for the VAS and Likert

		ALL-LOCF		MPOP-LOCF	
		Ralfinamide (n=169)	Placebo (n=92)	Ralfinamide (n=126)	Placebo (n=74)
VAS Ancova	Change Vs Baseline (±SD)	-18.1 (24.54)	-12.5 (20.13)	-20.1 (25.74)	-10.4 (20.62)
	Treatment Difference* (95% CI)	-5.2 (-11.0, 0.5)		-8.1 (-14.9, -1.4)	
	p-value	0.075		0.0187	
Likert (Pain) Ancova	Change Vs Baseline (±SD)	-1.7 (2.09)	-0.97 (1.85)	-1.8 (2.22)	-0.84 (1.96)
	Treatment Difference* (95% CI)	-0.7 (-1.18, -0.17)		-0.93 (-1.5, -0.3)	
	p-value	0.008		0.0026	
Daily Diary Sleep Ancova	Change Vs Baseline (±SD)	-1.27 (2.06)	-0.67 (2.09)	-1.5 (2.14)	-0.44 (2.13)
	Treatment Difference* (95% CI)	-0.57 (-1.06, -0.08)		-0.95 (-1.5, -0.37)	
	p-value	0.024		0.0014	
Daily Diary Activity Ancova	Change Vs Baseline (±SD)	-1.3 (2.37)	-0.8 (2.04)	-1.55 (2.51)	-0.72 (2.17)
	Treatment Difference* (95% CI)	-0.49 (-1.04, 0.06)		-0.76 (-1.4, -0.10)	
	p-value	0.079		0.024	

* Difference in LS Mean

Differences in the Responder Rate Analyses for the VAS and Likert

		ALL-LOCF		MPOP-LOCF	
		Ralfinamide (n=169)	Placebo (n=92)	Ralfinamide (n=126)	Placebo (n=74)
VAS	Responder Rate 50% n (%)	48 (28.4)	16 (17.4)	40 (31.7)	12 (16.2)
	Risk Difference (95% CI)	11.0 (0.7, 21.3)		15.5 (3.8, 27.2)	
	p-value	0.048		0.016	
Likert (Pain)	Responder Rate 50% n (%)	43 (25.7)	13 (14.0)	34 (27.4)	11 (14.7)
	Risk Difference (95% CI)	11.8 (2.1, 21.4)		12.8 (1.5, 24.0)	
	p-value	0.027		0.037	
Daily Diary Sleep	Responder Rate 50% n (%)	46 (27.7)	13 (14.0)	37 (30.1)	9 (12.00)
	Risk Difference (95% CI)	13.7 (3.9, 23.5)		18.1 (7.1, 29.0)	
	p-value	0.011		0.003	
Daily Diary Activity	Responder Rate 50% n (%)	47 (28.1)	17 (18.3)	39 (31.4)	14 (18.7)
	Risk Difference (95% CI)	9.9 (-0.5, 20.3)		12.8 (0.8, 24.8)	
	p-value	0.077		0.048	

Nerve Compression and Entrapment Syndromes; Distribution of Sub-diagnosis by Treatment

Neuropathic Pain Diagnosis	Ralfinamide	Placebo
Compression radiculopathy	32	17
Sciatic NC	1	1
Radial tunnel compression syndrome	1	0
Carpal tunnel syndrome	18	13
Median nerve entrapment	0	1
Cubital tunnel syndrome	1	1
Tarsal tunnel syndrome	0	3
Meralgia paresthtica	2	0
Other syndromes	5	3
Total	60	39

Mean Change in NCET patients (VAS and Likert for ALL-LOCF and MPOP-LOCF Populations)

		NCET-ALL-LOCF		NCET-MPOP-LOCF	
		Ralfinamide (n=57)	Placebo (n=39)	Ralfinamide (n=42)	Placebo (n=28)
VAS Ancova	Change Vs Baseline (±SD)	-24.91 (24.59)	-14.42 (19.85)	-25.0 (25.66)	-12.2 (20.5)
	Treatment Difference * (95% CI)	-9.5 (-19.0, 0.03)		-10.5 (-21.9, 0.86)	
	p-value	0.051		0.069	
Likert (Pain) Ancova	Change Vs Baseline (±SD)	-2.24 (2.23)	-1.28 (1.68)	-2.27 (2.38)	-1.18 (1.86)
	Treatment Difference* (95% CI)	-0.85 (-1.67, -0.03)		-0.95 (-1.92, 0.03)	
	p-value	0.042		0.057	

* Difference in LS Mean

Responder Rates in NCET patients (VAS and Likert for ALL-LOCF and MPOP-LOCF Populations)

		NCET-ALL-LOCF		NCET-MPOP-LOCF	
		Ralfinamide (n=57)	Placebo (n=39)	Ralfinamide (n=42)	Placebo (n=28)
VAS	Responder Rate 50% n (%)	26 (45.6)	8 (20.5)	19 (45.2)	5 (17.9)
	Risk Difference (95% CI)	25.1 (7.0, 43.2)		27.4 (6.7, 48.1)	
	p-value	0.012		0.018	
Likert (Pain)	Responder Rate 50% n (%)	24 (42.1)	7 (17.9)	16 (38.1)	5 (17.9)
	Risk Difference (95% CI)	24.2 (6.6, 41.7)		20.2 (-0.2, 40.7)	
	p-value	0.013		0.07	
Daily Diary Sleep	Responder Rate 50% n (%)	27 (47.4)	10 (25.6)	20 (47.6)	6 (21.4)
	Risk Difference (95% CI)	21.7 (2.9, 40.6)		26.2 (4.8, 47.6)	
	p-value	0.032		0.026	
Daily Diary Activity	Responder Rate 50% n (%)	25 (43.9)	9 (23.1)	18 (42.7)	6 (21.4)
	Risk Difference (95% CI)	20.8 (2.3, 39.2)		21.4 (0.1, 42.8)	
	p-value	0.036		0.064	

Ralfinamide Study 001: Conclusions

Ralfinamide:

- Was extremely well tolerated
- Did not show any clinically relevant or statistically significant changes for a wide variety of safety and tolerability assessments
- Showed in the ALL-LOCF analyses clinically relevant reduction of pain as assessed by the VAS and Likert scales; significant benefit was also demonstrated for pain, sleep, and impact in daily life activities using the daily pain diary
- In patients with pain due to NCET syndromes demonstrated clinically meaningful and statistically significant benefit

Ralfinamide in Nerve compression and entrapment

- No NP agent has previously been shown to be effective in this very large subpopulation (60% of NP diagnosis) of NP patients
- The multiple pharmacological actions of ralfinamide may explain this unique benefit
- Future studies in patients with chronic Neuropathic Low Back Pain (NLBP) syndromes, the most prevalent nerve compression conditions, are currently being planned

Nerve Compression & Entrapment Market

Epidemiology Basis

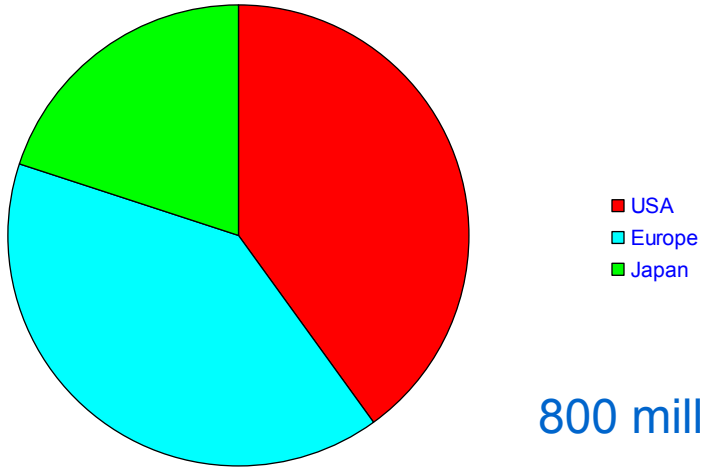
- Neuropathic Low Back Pain (NLBP), the most common clinical emergence of nerve compression, is mainly caused by neurological compressive syndromes such as lumbo-sacral radiculopathy, spinal stenosis, symptomatic spondilosis and sciatic nerve compression

- The estimated prevalence of NLBP is about **8% of the population**
  (Tarulli, 2007; Chau, 2007; Jarvik, 2002; Spalsky, 2004; Hsiang, 2006; Datamonitor, 2006; IMS Health, 2008)

- Nerve entrapment causes upper and lower limb mono-neuropaties such as the carpal tunnel syndrome, the ulnar nerve entrapment and tarsal tunnel syndrome

- Although limited epidemiological investigation has been addressed to nerve entrapment, this condition is thought to affect **4% of population**
  (Natahel, 2004; Tidy, 2007; IMS Health, 2008)

Clinical Ground in US, Europe and Japan

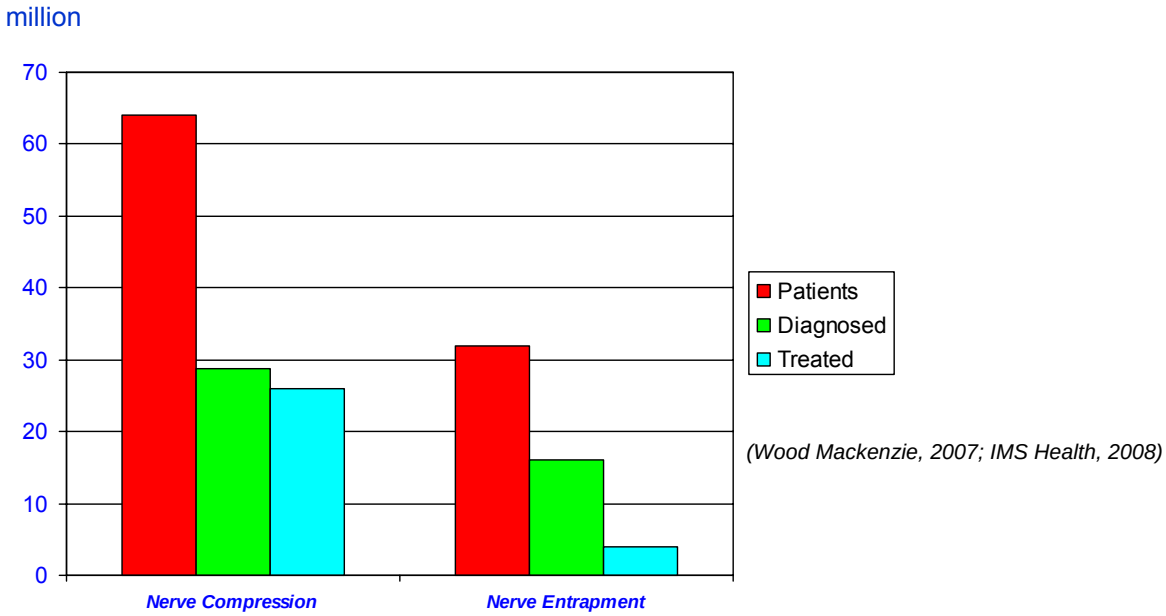


800 million people

8% affected by nerve compression → **64 million patients**

4% affected by nerve entrapment → **32 million patients**

Diagnosis & Treatment



(Wood Mackenzie, 2007; IMS Health, 2008)

About **28 million patients** are diagnosed and treated for nerve compression and nerve entrapment

Compliance to treatment, recoveries and relapses

(Wood Mackenzie, 2007)

80% → Patient compliance rate

95% → Three month recovery rate

40% → Six month relapse rate (*treated for additional 3 months*)

→ About 28 million treatments for 3 months / year in nerve compression

→ About 4 million treatments for 3 months / year in nerve entrapment

NCET is a highly promising market

- The large epidemiology of nerve compression and nerve entrapment associated with the high compliance rate of treated patients may allow a drug approved for these indication to reach a relevant number of captured patients in a relatively short time

- The existing diagnosis rates for nerve compression and nerve entrapment may be substantially increased under educational campaigns performed by companies marketing drugs approved for these indications

NCET is a unique market opportunity for ralfinamide

- No drugs are approved for neuropathic pain caused by nerve compression and nerve entrapment

- Nerve compression and nerve entrapment conditions are treated under off-label prescriptions with a number of classes of drugs i.e. anti-epileptics, narcotic and non-narcotic analgesics, NSAIDs, muscle-relaxants and anti-depressants. Nerve entrapment is also treated with non-drug options such as physical therapy and surgery

- Ralfinamide may become the first approved drug for nerve compression and nerve entrapment with great chances to exploit this condition through high selling prices and a fast market penetration

Ralfinamide Results in Post surgical (dental) pain

Post- surgical (Dental Pain) Study 002 – Rationale and Objectives

- Pilot phase II study to replicate significant benefits of pre- and post-surgery treatment seen in pre-clinical model
- Study model is treatment pre- (5 days) and post- (3 days) dental extraction surgery
- Objectives:
  - Safety: Tolerability of starting dose of 320 mg/day
  - Efficacy: Reduction in use of rescue medication (analgesics) and Patient's Global Assessment of Response to Treatment (PGART)

Study design

- Multi-centre, randomised, D-B, placebo-controlled, starting dose of 320 mg/day and target dose of 480mg/day
- Indication: patients with dental pain after third molar extraction
- Randomization: ralfinamide vs placebo 1:1
- Enrolment target: overall sample size of 174 patients
- Treatment duration: 8 days (5 days of pre-treatment with study medication 320 mg/day prior to the day of the molar-extraction surgery, 480 mg/day on the day of surgery and 320/160 mg/day for 2 days thereafter
- Countries: Romania; India

Demography and disposition

TOTAL PATIENTS ENROLLED	202	
NUMBER OF SCREEN FAILURES	15	
	Ralfinamide	Placebo
NUMBER OF PATIENTS RANDOMIZED	94	93
AGE (Yrs) mean ± std	28.0 ± 8.44	27.3 ± 7.21
Min-max	18-61	18-63
GENDER : male (female)	92 (2)	92 (1)
NUMBER OF PATIENTS DISCONTINUED *Reason For Discontinuation:*	5 (5.3%)	8 (8.6%)
Lost to follow-up		*2 (2.15%)*
Non compliance	*2 (2.1%)*	*2 (2.15%)*
Non serious adverse event	*2 (2.1%)*	
Other	*1 (1.1%)*	*2 (2.15%)*
Withdrawal of consent		*2 (2.15%)*

Safety: most frequent adverse events
(Reported in at least 2% of subjects in at least one group)

Adverse Event (Preferred term)	Ralfinamide (n=94)		Placebo (n=93)	
	N	%	N	%
Post procedural complication	18	19.15 %	17	18.3 %
Procedural site reaction	3	3.2 %	.	.
Conjunctivitis	2	2.1 %	.	.
Diarrhoea	1	1.1 %	3	3.2 %
Oedema*	2	2.1 %	1	1.1 %
Pyrexia	3	3.2 %	4	4.3 %
Trismus	6	6.4 %	5	5.4 %
Dizziness	7	7.45 %	4	4.3 %
Headache	3	3.2 %	2	2.15 %

N = number of patients; % = percentage of patients; *Reported in at least 2 % of subjects in at least one group; * Perimandibular Oedema

Efficacy measures

	RALFINAMIDE (N= 90)	PLACEBO (N=87)
Patients with rescue medication: Total (%)	65 (72%)	67 (77%)
PGART* (Good; very good; excellent)	70%	56.6%

*PGART: Patient Global Assessment of Response to Therapy

Safety and tolerability

- Starting dose of 320 mg/day well tolerated, no need of titration
- No statistically significant or clinically relevant differences from placebo in the results of any of the following:
  - Adverse events
  - Vital signs
  - Laboratory evaluations (blood chemistry, hematology, urinalysis)
  - Electrocardiogram (ECG)
  - Physical examination and neurological examination
  - funduscopy (with a picture of the fundus, if possible)
  - Corrected visual
  - Acuity, colour vision (Ishihara pseudo-isochromatic tables)
  - Visual field (Humphrey 24-2 or equivalent)

Summary

Conclusions

- Trial results demonstrate efficacy of Ralfinamide in peripheral neuropathic pain conditions
- Planned analysis demonstrates statistically significant and clinically relevant benefit in patients with NCET
  - largest sub-group of neuropathic pain patients
  - no other NP drug shown to be effective in this population
- Positive feedback from major health authorities on Phase III program in NLBP
  - NLBP trials to begin H2 '08
  - Post-surgical dental pain trials demonstrate starting dose of 320 mg/day well tolerated
  - NLPB trials will start at 320 mg/day; lack of titration suggests earlier onset of efficacy
- Ralfinamide may become the first approved drug for nerve compression and nerve entrapment with great chances to exploit this condition through high selling prices and a fast market penetration

Anticipated upcoming milestones

- Start of ralfinamide phase IIb/III study in neuropathic low back pain
- Safinamide phase III data in add-on study to L-dopa
- Start of phase I of HF1020 in Trident SPV
- Start of phase II trial with HF0220 in RA
- Completion of phase II safety and tolerability study with HF0220 in AD