DEVELOPING UNIQUELY DIFFERENTIATED DRUGS FOR CNS TARGETS

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Newron Pharmaceuticals

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Company Highlights

Unique portfolio of innovative CNS product candidates

- Xadago® for Parkinson's disease – Global approvals validate Newron's development capabilities from research to market
- Evenamide – New concept in treating inadequate/non-response in schizophrenia
- Ongoing search for strategically relevant assets

Significant near-term value drivers for both candidates

Management team with extensive experience and proven track record in drug development and commercialization

Fully funded beyond key value inflection points

- Cash balance of approx. € 40 million
- Access to long term funding facility of up to € 15 million (European Investment Bank)

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DEVELOPING UNIQUELY DIFFERENTIATED DRUGS FOR CNS TARGETS

Xadago® (safinamide)

Commercialized by partners in 15 European markets, the US, Canada and other markets for Parkinson's disease ("PD")

Newron receives milestone and royalty payments from sales of safinamide in PD; > € 50 million received to date

Evenamide (NW-3509)

Phase IIa trial demonstrated efficacy; potential first mechanistically validated treatment for poor/non-responding patients with schizophrenia

Preparing for initiation of Phase III program in two indications. Opportunities for commercialization by Newron (Clozapine TRS population) and partnering (major indication)

Innovative Clinical Pipeline with Near-Term Catalysts

PRODUCTS		Phase I	Phase II	Phase III	Market	Commercial Rights
Xadago® (safinamide)[1]	Adjunctive therapy in PD					Zambon
	Adjunctive therapy in PD					Zambon/Supernus
	Adjunctive therapy in PD					Meiji Seika/Eisai
	Levodopa Induced Dyskinesia (PD LID)					Zambon/Supernus
Evenamide (NW-3509)[1]	Adjunctive therapy in Schizophrenia					Newron
	Adjunctive therapy in Clozapine TRS					
Ralfinamide[1]	Orphan indication in neuropathic pain					Newron

Expected Milestones

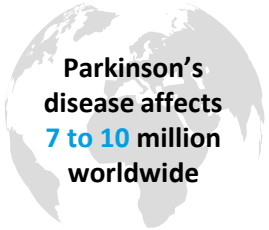
Xadago®:
Further launches expected
Study in patients with Levodopa Induced Dyskinesia (PD LID) expected to start early 2021

Evenamide:
Potentially pivotal studies expected to start early 2021

Ongoing search for strategically relevant assets

1 Safinamide, Evenamide and Ralfinamide all developed from Newron's ion-channel based research

Xadago®: 1st New Chemical Entity Approved in a Decade for Parkinson's Disease



Parkinson's disease affects 7 to 10 million worldwide

A progressive disorder, no cure available yet

- 2nd most common chronic progressive neurodegenerative disorder in the elderly
- Affecting 1-2% of individuals aged ≥ 65 years worldwide
  - **20%** to **30%** in early stage
  - **70%** to **80%** percent in mid to late stage
  - **>$4 billion** worldwide market

Fast and sustained efficacy, well tolerated

MID- TO LATE-STAGE PD PATIENTS –
add-on to L-Dopa dopamine replacement

- Significant improvement of
  - ON Time/OFF Time – regulatory endpoint
  - UPDRS II – activities of daily living
  - UPDRS III – motor function
  - CGI (clinical global impression) – severity and improvement
- Additional ON Time without any increase in any dyskinesia

Xadago®: New Label Study in Patients with Levodopa Induced Dyskinesia

- Zambon previously discussed with the US Food and Drug Administration (FDA) the design of a potentially pivotal efficacy study to evaluate the effects of Xadago®/safinamide in patients with PD LID
  - Intention is to perform the study in the US, Europe and Asia/Australia
- Given Newron's experience in the development of Xadago, Newron expected to conduct the study
  - Zambon remains associated with the study
- Newron to make a fixed financial contribution to the study, in return for a one-time milestone payment and a greater share of royalties should the study lead to a label extension
- Evidence indicating Xadago's anti-dyskinetic effect:
  - Mechanism, i.e. glutamate release inhibition
  - LID models in rats and monkeys
  - PD patient data: significant reduction of dyskinesia in 223 dyskinetic (Dyskinesia Rating Scale) PD patients in a 2-year, placebo-controlled study
- Study expected to start early 2021

Significant Commercial Opportunity in Xadago® (Safinamide)

US / Canada

Launched in US in 2017
Launched in Canada in 2019

EU

Latin America

Launched in Germany, UK, Italy, Spain and other EU territories, and Switzerland; regulatory approval for Brazil, Colombia, UAE; application for regulatory approval filed for Mexico

Israel

Application for regulatory approval filed

Japan / Asia

Launched in 2019

Australia /New Zealand

Launched in Australia in 2019

- Parkinson's disease affects 7 to 10 million people worldwide
- Long period of Xadago® market exclusivity (patent life: 2029 in EU, 2031 in the US)
- Milestone and royalty revenues to Newron since 2012

Schizophrenia: No Effective Treatment for the Last 20 Years to Reduce Burden of Disease

Globally over 4 million patients

- Disease onset in 20s, need for life-long treatment
- Cost to society (direct cost US only): $63bn p.a.

Efficacy of current treatment options is insufficient

Onset of disease occurs in early adulthood affecting 1% of the population worldwide

- Most patients with schizophrenia demonstrate reduced response to typical and atypical antipsychotics after few years of treatment
- 64-82% of chronically treated patients switch treatments but without additional benefits, no significant reduction in side-effects
- Treatment-resistant schizophrenia (TRS)
  - Min. 30% of patients after 3-5 years are TRS: only clozapine shows efficacy
  - 30-50% of these patients show resistance to clozapine; no therapeutic option left
- New data indicate far worse prognosis than current concepts:
  - Outcome after one year for young US patients on treatment following first episode: 24 times greater mortality than age matched (16-30 years old) controls (Schoenbaum, 2017)

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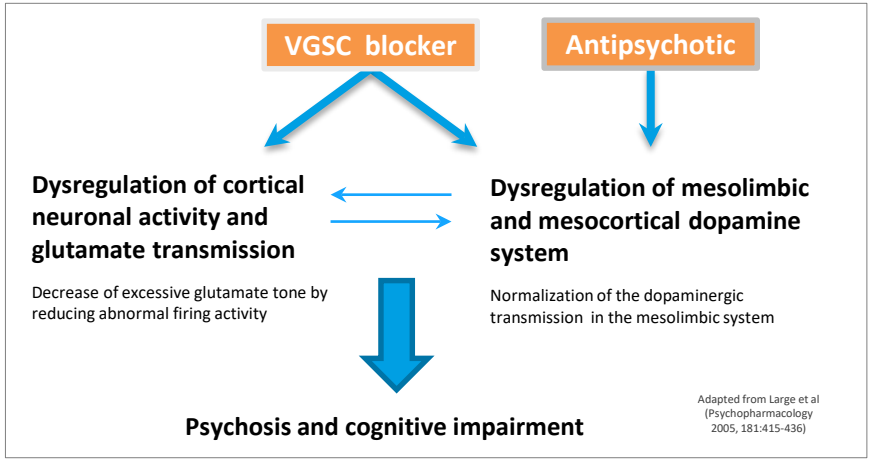
Evenamide Novel MoA: Synergistic with Marketed Antipsychotics

- Evenamide, a Voltage-Gated Sodium Channels (VGSC) blocker has the potential to target the abnormal neuronal activity and glutamate transmission in patients with schizophrenia
- Evenamide may add to or synergize with antipsychotic drugs to bring about a combined therapeutic effect on glutamate and dopamine systems
  - Effects seen in combination with haloperidol, risperidone and aripiprazole
- Composition of matter – USPTO, 2013 – patent life 2028 plus extension

Voltage-Gated Sodium Channels (VGSC) blockers may act synergistically with antipsychotics in schizophrenia therapy



Evenamide's Unique MOA Demonstrated

Selectively blocks native sodium channels, showing no off-target effect on >130 CNS receptors, enzymes, transporters, etc.

Selectively blocks VGSCs in a voltage-and use-dependent manner

Inhibition of native sodium channels expressed in rat cortical neurons

K_{rest} (µM)

25

K_{inact} (µM)

0.4

Modulates sustained repetitive firing without inducing impairment of the normal neuronal excitability

High frequency firing

Control

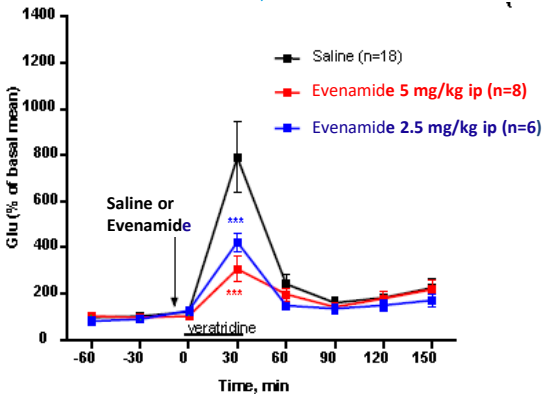
Evenamide 1µM

Low frequency firing

Control

Evenamide 1µM

Inhibits Glutamate Release



Evenamide is Active in a Wide Range of Schizophrenia and Psychiatric Animal Models as a Monotherapy and as an Add-on to Existing Antipsychotics

		Monotherapy	Add-on
Information Processing Deficit	Pre-pulse inhibition (PPI) disrupted by dopamine activation (amphetamine -rat)	✓	✓
	Pre-pulse inhibition (PPI) disrupted by NMDA antagonists (MK-801, PCP, -rat)	✓	
	Pre-pulse inhibition (PPI) disrupted by natural stimuli (sleep deprivation -rat)	✓	
	Pre-pulse inhibition spontaneous deficit (C57 mice)	✓*	✓
	Pre-pulse inhibition (PPI) disrupted by Ketamine in rat	✓	✓
Negative Symptoms	PCP-induced deficit in Social Interaction in the rat	✓	✓
	Saccharin preference test (anhedonia) in prenatal poly:IC exposed mice (ongoing)	✓	
	Three-chamber sociability test in prenatal poly:IC exposed mice (ongoing)	✓	
	Forced swimming test (avolition) in prenatal poly:IC exposed mice (ongoing)	✓	
Psychosis and Mania	Amphetamine induced hyperactivity in mice	✓	✓
	Amphetamine plus Chlordiazepoxide induced hyperactivity in mice	✓	✓
Cognitive Impairment	Novel object recognition in the rat: short term scopolamine impairment	✓	
	Novel object recognition in the rat: long term 24 hr natural forgetting	✓	
Impulse Control and Mood Symptoms	Resident–Intruder test in mice (Impulsivity)	✓	
	Tail suspension test in mice (Depression)	✓	
	Marble burying test in mice (Obsessive Compulsive Disorders)	✓	

*Trend
Blank cells = not evaluated

Evenamide: Proof of Concept in Patients with Schizophrenia Demonstrated

- 4-week, placebo-controlled, add-on study of evenamide (15-25mg BID/day) in 89 patients on stable doses of aripripazole or risperidone showing signs of worsening when compared to standard of care, at every assessment during the study (starting day 8)

  - **Significant improvement of**
    - PANSS positive, both mean change AND responder rate
    - CGI-C

  - **Superior benefit on**
    - PANSS total
    - LOF total
    - CGI-S

- Glutamatergic MoA seems to improve symptoms of psychosis in patients not responding to D2/5HT2 blockade

Evenamide: Regulatory Interactions and Phase III Clinical Development Plan

Health Authorities (Spain, Denmark, Sweden, Germany, UK, CHMP, US, Canada) in agreement with proposed Phase III plan

Newron aims to complete additional informative studies, requested by the FDA, to allow for its Phase III to commence in early 2021, with results expected 18 months after initiation

- Preclinical part of safety work has been successfully completed; no toxicity issues reported; submitted to FDA, already
- First clinical safety study initiated in July 2020
  - Four week, randomized, double-blind placebo-controlled study
  - To evaluate safety, tolerability, EEG effects, preliminary efficacy of 7.5 mg and 15 mg BID
  - Outpatients suffering from chronic schizophrenia being treated with one of the leading anti-psychotics
  - Approximately 120 patients to be randomized, 13 study centers in the US and India
  - Currently, more than 140 patients screened, 91 randomized, 63 completed

Evenamide: Regulatory Interactions and Phase III Clinical Development Plan

Phase III program will be comprised of two pivotal studies in specific populations:

- **Non-treatment resistant patients**: chronic schizophrenics experiencing inadequate benefit for symptoms of their psychosis, on current atypical antipsychotic monotherapy (risperidone, aripiprazole, paliperidone, olanzapine, or quetiapine) **– Planned Study 003**
- **Treatment resistant schizophrenia**: Patients whose psychotic symptoms are not responding adequately to treatment with clozapine - **Planned Study 004**

Positive results of both studies would meet efficacy criteria for both indications

- Positive result of study 004 only would lead to approval of clozapine-resistant population only
- Positive result of study 003 only would lead to need for another similarly designed study

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