SPECIALIST IN CNS DRUG DEVELOPMENT

INNOVATIVE TREATMENTS TO IMPROVE QUALITY OF LIFE

11th Baader Investment Conference
September 23, 2022

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 € 28.4 million (June 30, 2022)
- Royalty income, R&D tax credit: approx. €16m (2 yrs.)
- Cash reach 2024

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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 TRS				
Ralfinamide[1]	Orphan indication in neuropathic pain				Newron

Expected Milestones

Xadago®:
Preparations for study in patients with Levodopa Induced Dyskinesia (PD LID) ongoing, study expected to start 2023

Ongoing search for strategically relevant assets

Evenamide:
- Safety, tolerability and preliminary efficacy, six-week, randomized, rater-blinded study in TRS patients (study 014) >150 patients, 100 pts. interim results presented at CINP, June 2022, final results expected in QI 2023
- Minimally 200 pts phase II/III study started Sept. 2021, results expected in HYI 2023, further pivotal study to initiate in 2023

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

What differentiates Evenamide in schizophrenia

- LARGE MARKET
- UNIQUE MOA AND POSITIONING
  - First **anti-psychotic add-on** drug
    - **Change** a **non-responder** into a **responder**
    - No need to change current therapy, minimizing risk of patient relapse
    - **Ease-of-use** for patients & physicians
  - First **TRS add-on** drug
  - Opportunity to keep niche indication for commercialization/role in commercialization of TRS indication
- POSITIVE PHASE II IN NON-TRS
- 1 OF 2 PIVOTAL STUDIES (NON-TRS) ONGOING
- PILOT STUDY IN TRS ONGOING
- CHANCE FOR EARLY MARKET ACCESS
- EXCLUSIVITY (2033 AND BEYOND)

SCHIZOPHRENIA: 20 MILLION PATIENTS WORLDWIDE (1% PREVALENCE) WITHOUT EFFECTIVE DRUG TO ELIMINATE SYMPTOMS, REDUCE PROGRESSION, LIMIT DISABILITY, SUICIDE OR EARLY MORTALITY

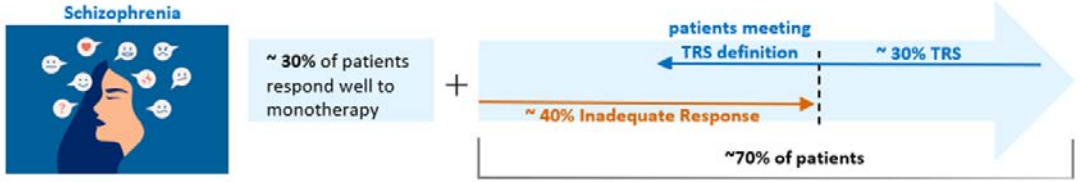
VAST MARKET OPPORTUNITY
(anti-psychotics market >$23bn)

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

Over 30 antipsychotics available, but all provide short-term and insufficient relief of some of the symptoms, only

Patients need medication from disease onset (18 years) for next 50 +years (life long)

Most patients with schizophrenia demonstrate reduced control of positive symptoms by typical and atypical antipsychotics after first few years of treatment, and no improvement of negative/cognitive symptoms or diminished functioning



- Major Shortcomings of Current antipsychotics:
  - All target D2/5HT2, but not glutamate, shown lately to be the major abnormality in poor/non-responders
  - All rely on D2/5HT2 monotherapy without considering benefit of additive glutamate inhibition
- Current antipsychotics are mostly off patent or close to patent expiry, with significant side effects (weight gain, hormonal changes, cognitive/sexual dysfunction)

EVENAMIDE – THE COMMERCIAL OPPORTUNITY

Addresses medical need in key sub-populations, COM: 2033 (WW), 10 yrs exclusivity post approval (EU)

- First **add-on** antipsychotic to be approved for **inadequately responding** or **treatment resistant** patients
  - Chronic schizophrenia population every (on average) 18 months (CATIE study), due to fading efficacy and side effects of current medication
  - Add-on therapy with **no dose-limiting side effects** a key advantage for patients and prescribers
- **First drug for treatment of TRS** since clozapine (1989)

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

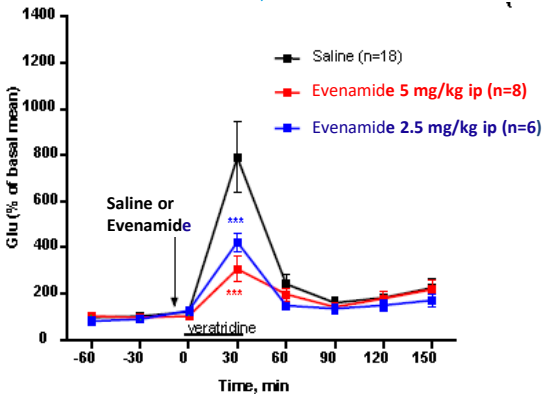
Evenamide 1µM

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	✓	✓
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

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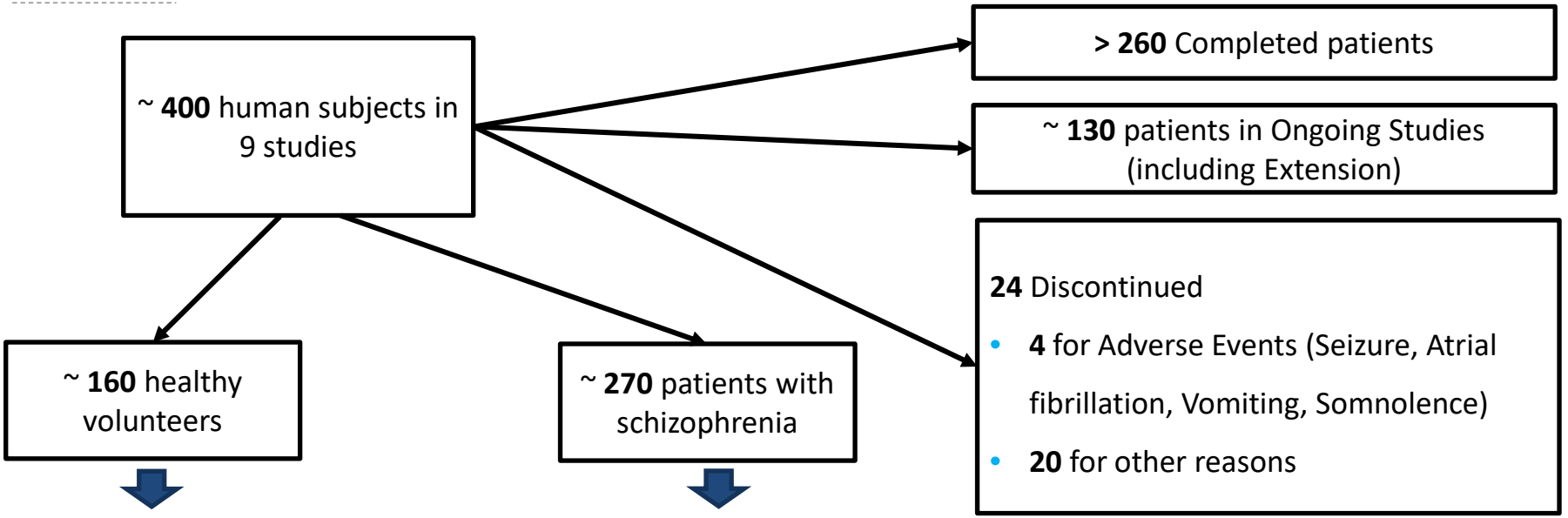
DISPOSITION OF SUBJECTS EXPOSED TO EVENAMIDE AND MOST FREQUENT (>3%) TREATMENT EMERGENT AES



Most frequent (>3%) AEs:

- Headache → 7.5%
- Dizziness → 6.3%
- Abdominal pain/discomfort → 3.1%

Most frequent (>3%) AEs:

- Somnolence → 5.5%
- Headache → 3.7%
- Insomnia → 3.3%

CONCLUSIONS

- Single doses of evenamide up to 60 mg in healthy volunteers, and multiple doses up to 30 mg bid in patients with schizophrenia receiving antipsychotics, were well tolerated with no safety issues identified
- TQT study in HVs indicated that evenamide is devoid of risks of QTc prolongation (evenamide maximal increase was <6 msec; placebo 7.6 msec) or arrhythmias
- To date, ~ 400 subjects have been treated in Phase I-III trials without any evidence of EPS, metabolic syndrome, sexual disfunction, significant CNS events, or laboratory abnormalities
- The emerging, favourable safety profile of evenamide indicates it could be added to any current APs in patients with schizophrenia without any risk of drug-drug interaction or additional toxicity

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 aripiprazole 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

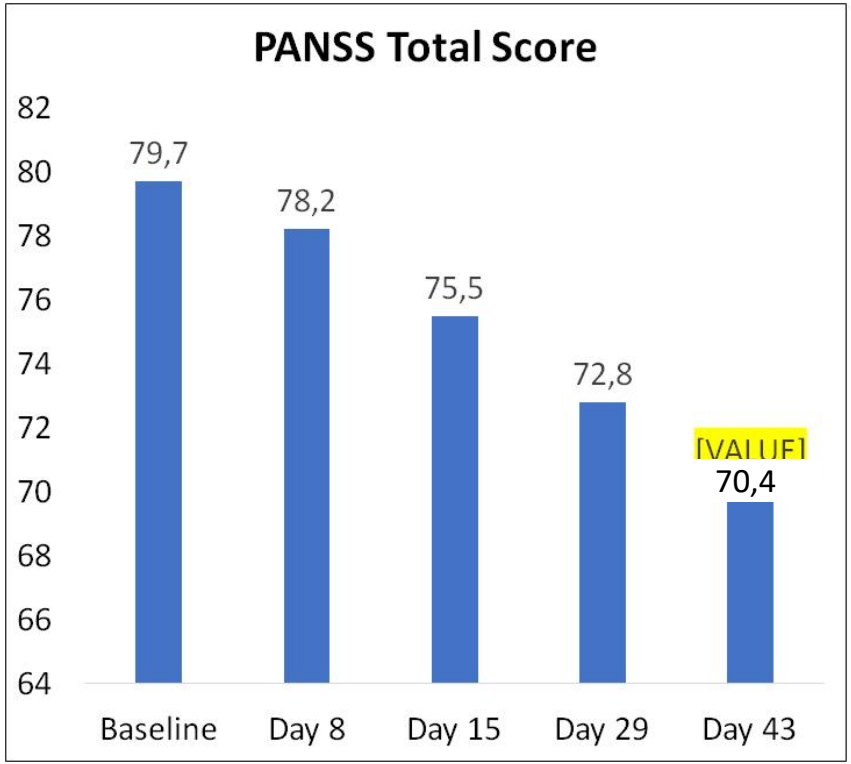
EVENAMIDE: REGULATORY INTERACTIONS

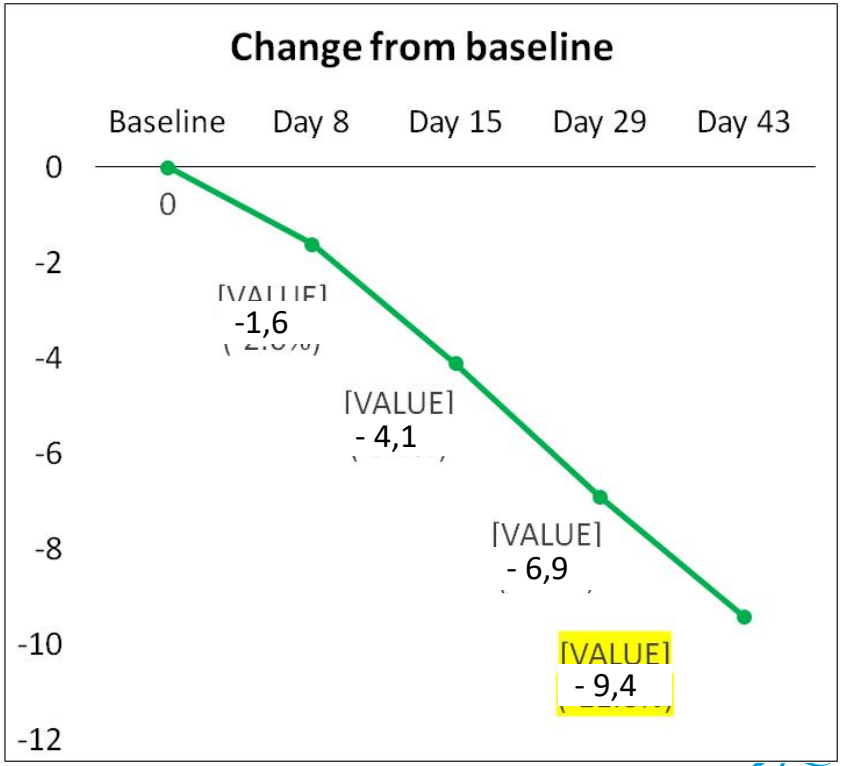
Health Authorities (Spain, Denmark, Sweden, Germany, UK, CHMP, US, Canada) in agreement with proposed Phase III plan

Newron providing additional informative studies as requested by the FDA prior to allowing Newron to initiate its Phase III development program

- Preclinical part of safety work has been successfully completed; no toxicity issues reported; submitted to FDA, already
- First 4-week clinical safety (EEG) study completed in March 2021 (Study 008); 138 patients-no safety issues
- Following recent discussions with FDA, Newron will address the remaining FDA issues once data from studies 014 and 008A studies are available
- Safety, tolerability and preliminary efficacy, six-week, randomized, rater-blinded study in TRS patients" (study 014)
  - Outpatients suffering from TR schizophrenia not responding adequately to an antipsychotic
  - >150 pts to be randomized fixed doses of 7.5, 15, and 30 mg bid in 20 study centers in the EU and ASIA,
  - First results presented at CINP in June 2022, final results expected in QI 2023

EFFICACY: PANSS TOTAL SCORE BY VISIT AND CHANGE FROM BASELINE





EFFICACY: CGI-S & CGI-C OVER TIME

Visit	CGI-S		CGI-C
	Mean Rating	Mean Change from Baseline	Mean Rating
Baseline	4.6	-	-
Day 8	4.5	-0.1	3.8
Day 15	4.3	-0.3	3.5
Day 29	4.0	-0.5	3.2
Day 43	3.9	-0.7	3.0

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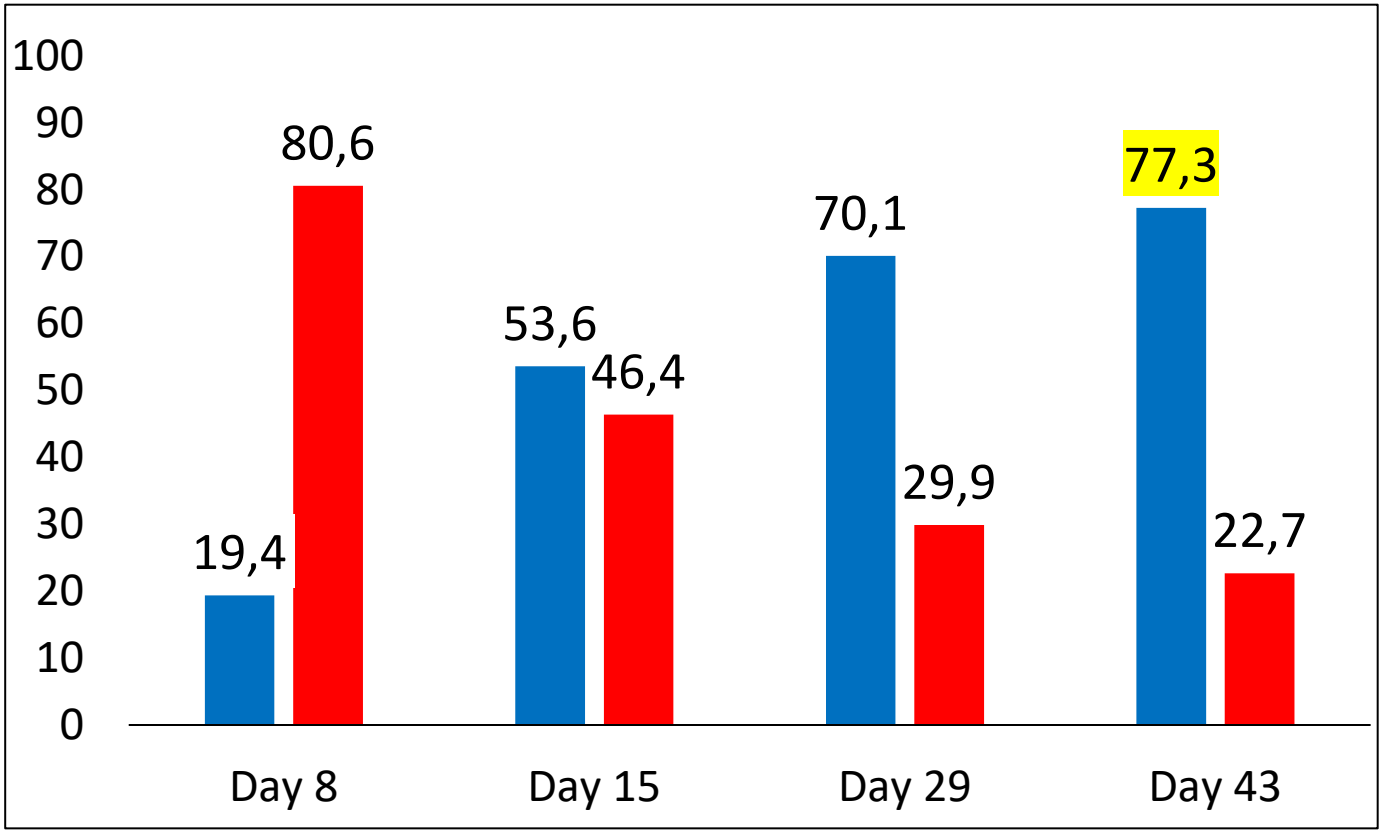
EFFICACY: CGI-C RESPONDER RATE



Responders:
- Very much improved
- Much improved
- Minimally improved

Non-Responders:
- No change
- Minimally worse
- Much worse
- Very much worse

CONCLUSIONS

- Add-on of evenamide to all antipsychotics was well tolerated with few new adverse events
- PANSS total, CGI-S, LOF, and MSQ show gradual improvement over time at doses used; likely that higher doses (30 mg bid) would show greater benefit
- **CGI-C** ratings, performed by the same psychiatrist who rated the PANSS, indicated a high proportion (~ 77%) of "**responders**" (very much, much, and minimally improved) while the reduction in PANSS was modest, ~ 12%
- This indicates the treating psychiatrists rating of the CGI-C is based on recognition of benefits of evenamide that are not fully captured in the **PANSS**
- The improvement in LOF and MSQ at Day 43 was indicative of an overall improvement in functioning, and a greater patient satisfaction with background medication + evenamide compared to background medication alone, respectively.
- 97% completed 6-week treatment period with 90% continuing in extension study

EVENAMIDE: PHASE III CLINICAL DEVELOPMENT PLAN FOR SCHIZOPHRENIA INDICATION

Phase III program will cover 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)
- **Treatment resistant schizophrenia**: Patients whose psychotic symptoms are not responding adequately to any second-generation antipsychotic

First potentially pivotal Phase II/III safety and efficacy study 008A **(non-TRS)** in Europe, Asia and Latin America

- Four-week, randomized, 30mg bid versus placebo double-blind study to enroll> 200 patients ongoing
- Chronic moderate to severe schizophrenia patients on one of the leading 2nd generation anti-psychotics
- Start of study September 6, 2021, results expected by QIV 2022

Second potentially pivotal Phase II/III safety and efficacy study 003 **(TRS)**

- Eight-week, randomized, double-blind placebo-controlled Global study in >450 TRS patients
- Outpatients suffering from TRS being treated with one of the leading 2nd generation anti-psychotics
- Start of study by end 2022, results expected in early 2024

Option to add mania/mixed episodes indication for initial submission

Xadago in PD Marketed compound with opportunity for second label

- FIRST APPROVED NCE IN >10 YRS (US, EU)
- GLOBALLY LICENSED
- DOUBLE DIGIT/SINGLE DIGIT % ROYALTIES
  >€65M MILESTONES/ROYALTIES COLLECTED
- TO REACH PEAK COMMERCIAL POTENTIAL, GET SECOND LABEL FOR LID IN PD
  - 40% OF PD PATIENTS
  - ONLY 1 APPROVED DRUG (US, ONLY)
  - STUDY TO START IN 2022
  - ATTRACTIVE FINANCIAL TERMS

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 (2015), Switzerland, UAE, Brazil and Colombia; application for regulatory approval filed for Mexico

Israel

Approved in 2020

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); ANDAs filed QII/2021
- Milestone and royalty revenues to Newron since 2012

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