Ovid Therapeutics

Corporate Overview

(NASDAQ: OVID)

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JANUARY 2023

Disclaimers and forward-looking statements

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including, without limitation, statements regarding the timing and development of Ovid's product candidate pipeline and achievement of expected near- and long-term milestones; the potential therapeutic benefits of Ovid's current or future product candidates and pipeline programs; the reporting of preclinical data for OV329; the reporting of data for Phase 1 study in healthy volunteers for OV329; the potential use of OV329 to treat rare and treatment-resistant forms of epilepsy and seizures; the clinical and regulatory development of OV329, including the anticipated timing of clinical trials of OV329 and other KCC2 compounds in the Company's library; the likelihood that data for OV329 will support future development and therapeutic potential; the potential development of OV350; the suitability of the Company's library of novel, direct KCC2 transporter activators for a range of formulations and administrations that would make it possible to pursue both chronic and acute epilepsies; the timing for filing of the Company's IND applications; the potential benefits of Gensaic's proprietary phage-derived platform; the timing for the completion of Takeda's two pivotal Phase 3 trials evaluating soticlestat for Lennox-Gastaut and Dravet syndromes; the success of Takeda's trials in soticlestat; the duration of the Company's cash runway, and the expectation that it will support the advancement of the Company's pipeline; Ovid's business development intentions; the success of any licensing or partnering opportunities, the success, timing, ability to attract and maintain strategic collaborations; the clinical and regulatory development and potential commercialization of soticlestat, OV350, or any of Ovid's other current or future product candidates and pipeline programs and market opportunities You can identify forward-looking statements because they contain words such as "will," "plan", "believes", intends," "anticipates," "strives," "pursue," "design," "advance," "target," "seek," "expects," and "potential" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances).

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Ovid® Therapeutics

Transforming the lives of individuals with epilepsies & rare neurological diseases



Focused epilepsy pipeline
with significant unmet need & large addressable market



Substantial milestones & royalties
due from Takeda surrounding potential regulatory approval & commercial sales of soticlestat



Veteran team
with track record of value creation & transformative transactions



Cash runway into 2025
& disciplined approach to business development

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Epilepsy market is a promising opportunity

Significant patient need

30 – 40%
of individuals have seizures not controlled with anti-seizure medicines[1]

47%
of patients take 5 medicines on average, demonstrating need for unique, well tolerated anti-seizure mechanisms[2]

De-risked development

Validated & emerging targets cause neuronal hyperexcitability

Small molecules that can cross the blood-brain barrier

Predictive, clinically-translatable seizure models

Hard endpoints (seizures) and biomarkers

Large addressable market

65 million
people living with epilepsy worldwide[3]



3 million
people living with epilepsy in US[4]

>$8B
global market opportunity[5]

1. Huron Primary Research (11/2019-12/2019)
2. Terman SW, Aubert CE, Hill CE, et al. Polypharmacy in patients with epilepsy: a nationally representative cross-sectional study. *Epilepsy Behav.* 2020;111:107261.
3. Epilepsy fast facts. Centers for Disease Contr Easl and Prevention. Updated September 30, 2020. Accessed July 12, 2022. https://www.cdc.gov/epilepsy/about/fast-facts.htm.
4. CDC Epilepsy data: https://www.cdc.gov/epilepsy/data/index.html
5. Global Data Report, Epilepsy: Global Drug Forecast and Market Analysis to 2030 – Forecast Update

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Advancing epilepsy pipeline

Small molecule

Genetic target

SMALL MOLECULE	INDICATION/TARGET	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	ANTICIPATED MILESTONES
OUT-LICENSED TO Takeda **SOTICLESTAT** CH24H inhibitor	Dravet syndrome					• Phase 3 data from 2 registrational trials • Filing marketing authorization submissions in Takeda's FY 2024
	Lennox-Gastaut syndrome					
OV329 GABA-aminotransferase inhibitor	Tuberous Sclerosis Complex, infantile spasms and focal seizures					• Phase 1 target engagement & safety findings - H1 2024
IN-LICENSED FROM AstraZeneca **OV350** KCC2 transporter activator	Resistant epilepsies and other neuro-pathologies					• Anticipated IND in 2024

NUCLEIC ACID	INDICATION / TARGET	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MILESTONE
OV882 *Collaborator: UCONN*	Angelman syndrome					
OV815 *Collaborator: Columbia Univ.*	KAND – KIF1A associated-neurological disorders					
OV825 *Collaborator: Columbia Univ.*	HNRNPH2					
UNDISCLOSED PROGRAMS WITH COLUMBIA UNIVERSITY & RESEARCH COLLABORATION WITH GENSAIC						

STRATEGIC BUSINESS DEVELOPMENT ACTIVITIES FOCUSED ON COMPLEMENTING OUR GENETIC TARGETS & AUGMENTING CLINICAL STAGE ASSETS

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A franchise of potential, small molecule epilepsy medicines

Programs with differentiated best-in-class or first-in-class mechanisms of action

	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3

IN-LICENSED

OV329

Northwestern University

Potential best-in-class, oral GABA-aminotransferase(GABA-AT) inhibitor with an enhanced benefit/risk profile and administration in preclinical development for focal seizures, tuberous sclerosis and infantile spasms; in a Phase 1A study in healthy volunteers

OV350 & KCC2 PORTFOLIO

AstraZeneca

Potential first-in-class KCC2 direct activator – and a library of novel, direct KCC2 activators for resistant epilepsies and other CNS indications in-licensed from AstraZeneca

OUT-LICENSED

SOTICLESTAT

Takeda

A novel 24-cholesterol hydroxylase inhibitor for Dravet & Lennox-Gastaut syndromes out-licensed to Takeda in transaction that can generate up to $856M in total upfront & milestones payments (including $196M previously paid)[1]

1. In 1H 2021

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Team of disciplined operators & value creators



Jeremy Levin
D. Phil, MB BChir
Chairman, CEO



Julia Tsai, Ph.D.
Head, Clinical Development & Medical



Claude Nicaise, M.D.
Head, Research & Development



Manoj Malholtra, M.D.
Medical Affairs



Jeffrey Rona
Chief Business & Financial Officer



Jason Tardio, MBA
Chief Operating Officer



Tom Perone, MBA, J.D.
General Counsel, Corporate Secretary, Chief Compliance Officer



Meg Alexander
Chief Corporate Affairs Officer

- **Transformative transactions**
  Invested ~$83M in soticlestat to secure $196M in upfront payment & potential milestones of up to $660M and tiered royalties up to 20%
- **Track record of expedited development**
  Completed soticlestat Phase 2 six months ahead of schedule and under budget
- **Experience from 25+ launches, including 4 CNS blockbusters**
- **Deep knowledge from development & launch of multiple epilepsy medicines**

Contributed to development & launch:

TYSABRI (natalizumab)
Ztalmy (ganaxolone) oral suspension 50 mg/mL
GILENYA (fingolimod) capsules 0.5mg
Revlimid (lenalidomide)
SPRYCEL dasatinib
Fintepla (fenfluramine) 2.2 mg/mL oral solution
Brineura (cerliponase alfa)
SPINRAZA (nusinersen) injection 12 mg/5 mL
Tecfidera (dimethyl fumarate) delayed-release capsules 240 mg

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Progress & milestones

Recent accomplishments

- **Out-licensed soticlestat** to Takeda for Dravet & Lennox-Gastaut syndromes (LGS), with $196M upfront payment; and up to: $660M in milestones and 20% royalties
- **In-licensed** KCC2 portfolio to strengthen epilepsy franchise from AstraZeneca
- **Initiated Phase 1 trial** of OV329
- **Streamlined company** to preserve strong cash position to support corporate goals
- **Bolstering management team** with experts in epilepsy development

Near-term milestones

- **Phase 3 data of soticlestat** in Dravet & LGS anticipated *prior* to global regulatory filings by Takeda in its FY 2024
- **OV329 Phase 1 SAD & MAD data** expected in H1 2024
- **Anticipated IND submission** for KCC2 portfolio (OV350) in 2024
- **Licensing activities** to focus & complement pipeline with clinical-stage assets

Long-term vision

- **A leading anti-seizure franchise** with differentiated medicines to serve a portion of >$8B market
- **Fully integrated biotech company** with multiple commercial & clinical stage CNS programs
- **Genetic epilepsy programs** advance into the clinic
- **Business development** to reach global epilepsy market opportunity

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OUT-LICENSED TO TAKEDA

OVERVIEW: soticlestat

Potential first-in-class cholesterol 24-hydroxylase inhibitor for treatment resistant epilepsies[1]

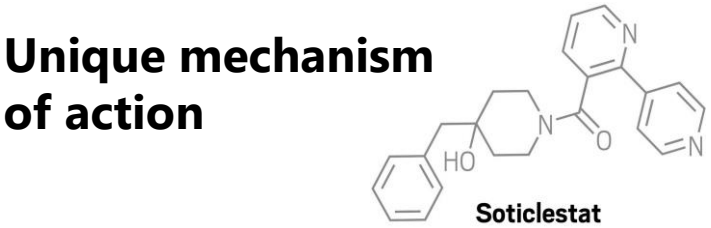
Actively being studied in two pivotal, Phase 3 trials

(conducted by Takeda):

- Dravet syndrome (DS)
- Lennox-Gastaut syndrome (LGS)

Designed to reduce seizure susceptibility & improve seizure control[2]

Unique mechanism of action



Soticlestat

- Reduces glutamatergic signaling & reduced inflammation[1,3]
- Dose dependent response[1,3]

Potential to be used in early treatment lines[2]

- Based upon promise of seizure control efficacy and tolerability profile observed in clinical trials
- No monitoring anticipated for soticlestat as is required for other new anti-seizure medicines[4]

Encouraging safety & tolerability profile in Phase 2 trials[2]

- Main adverse events for soticlestat over placebo are lethargy/somnolence and constipation
- No anticipated monitoring needs

Target regulatory approval filing by Takeda anticipated in its fiscal year 2024[4]

1. Nishi T, et al. AAN 2018.
2. Hahn et al. A phase 2, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of soticlestat as adjunctive therapy in pediatric patients with Dravet syndrome or Lennox–Gastaut syndrome (ELEKTRA). Epilepsia. 2022; 00: 1– 13. https://doi.org/10.1111/epi.1736
3. Salamone A, et al. ECE 2018 [4] FINTEPLA prescribing information label, pages 5-8.
4. Takeda's FY2022 Q2 Earnings Announcement dated October 27th, 2022.

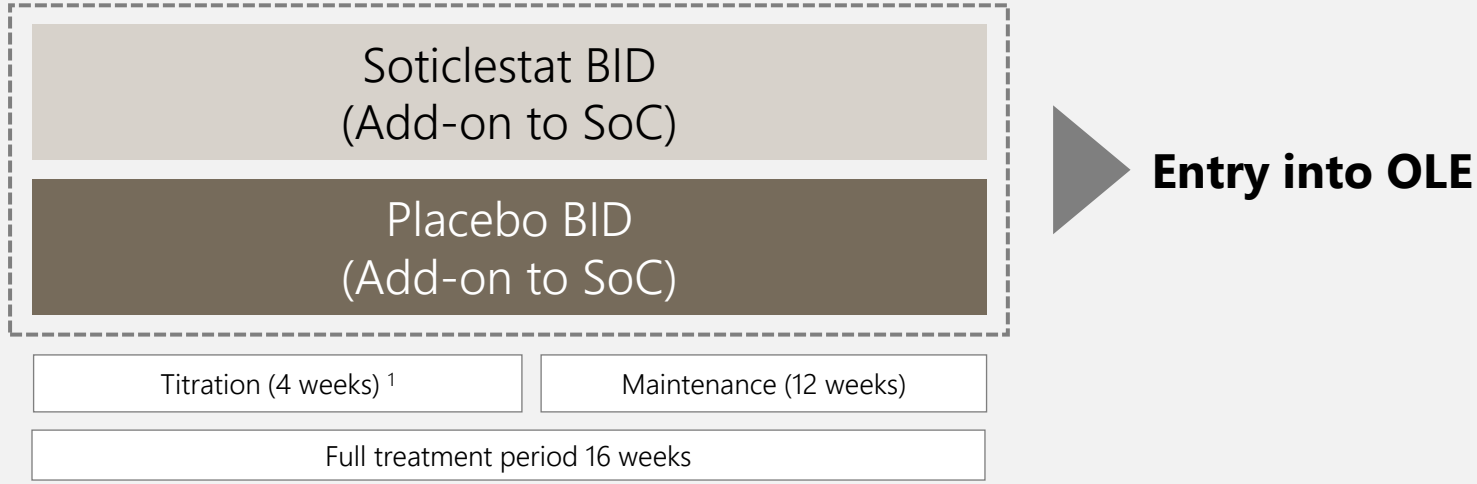
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Phase 3 placebo-controlled studies in DS & LGS

Trials currently being conducted by Takeda

SKYLINE: DS N = 142

SKYWAY: LGS N = 234



TRIAL DESIGN

- Trial design based on feedback from FDA, EMA & PMDA
- Ages ≥ 2 years
- Adjunctive to ASMs
- Active seizures at baseline[2]

OUTCOME MEASURES

Primary

- Frequency change in convulsive seizures (DS study) during full treatment period
  - DS: ≥4 convulsive seizures at baseline
- LGS study uses Major Motor Drop seizure endpoint (frequency change in major motor drop seizures) during full treatment period
  - LGS: ≥8 Major Motor Drop (MMD) seizures at baseline.
  - For LGS, countable drop seizures reliably recognized by the caregivers and consistently implemented by the investigators

[1]100 mg BID, 200 mg BID, 300 mg BID (mg/kg dosing)
[2]Clinical Trials.gov Accessed October 26, 2021.

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Status update: Soticlestat registrational trials

As of December 9, 2022

skyway STUDY

A Study of Soticlestat as an Add-on Therapy in Children, Teenagers, and Adults With Lennox-Gastaut Syndrome

112 sites worldwide[1]

75 active recruiting • 27 expected to be recruiting

skyline STUDY

A Study of Soticlestat as an Add-on Therapy in Children and Young Adults With Dravet Syndrome

98 sites worldwide[1]

59 active and recruiting • 29 expected to be recruiting

TAKEDA guides to regulatory filings in its fiscal year 2024 (begins April 2024); following Phase 3 data for both indications

[1] Clinical Trials.gov updates as of December 9, 2022. Approximately 10 sites in Russia and Ukraine are considered "active; not recruiting"
Skyway: https://clinicaltrials.gov/ct2/show/NCT04938427
Skyline: https://clinicaltrials.gov/ct2/show/NCT04940624

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Soticlestat agreement with Takeda holds value of up to $856M[1], creating an expected non-dilutive cash stream

Invested ~$26M upfront & $57M in clinical development

2021	2025*	Est. 2025 and later
Upfront payment • All Ovid financial obligations for soticlestat are terminated	**Expected regulatory decision milestone(s)** • Takeda funding comprehensive LGS and Dravet trials • Soticlestat is leading neuroscience Phase 3 program for Takeda[2]	**Commercial milestones & royalties** • Tiered double-digit royalties on ALL indications • Up to 20% on GLOBAL soticlestat sales
$196M (Q1'21)	**Up to $660M in additional milestones⁺ + Royalties (up to 20%)** ⁺Potential for combined regulatory and commercial milestone payments	

ROYALTY & MILESTONES TO FUND PIPELINE & BUSINESS DEVELOPMENT

*Based upon (i) estimated primary completion of two, pivotal Phase 3 trials by March 2024, as disclosed by Takeda in materials in July 2022. Takeda disclosed that it anticipates regulatory filings in its fiscal year 2024.

[1] $856M includes the $196M already received as an upfront payment in 1H 2021
[2] Takeda Consolidated Development Pipeline by Phase Presentation. Accessed November 2022.

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OVERVIEW:

OV329

A potential best-in-class GABA-aminotransferase inhibitor for treatment of rare adult & pediatric epilepsy disorders

OV329's enhanced potency may deliver:

- Increased seizure reduction efficacy
- Improved safety profile (better ocular safety margin than vigabatrin in preclinical studies)
- Preferred dosing

Demonstrated anti-seizure activity in 6 separate animal models

Multiple possible applications:

- Seizures associated with Tuberous Sclerosis Complex (TSC)
- Infantile spasms
- Conditions with focal seizures

Phase 1 study active

- Findings including potential indicator of efficacy & safety expected H1 2024

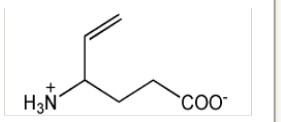
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A potent, next-generation GABA AT-inhibitor

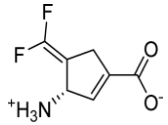
OV329 — **Believed to act upon a validated anti-seizure target to increase GABA and reduce neuronal hyperexcitability**

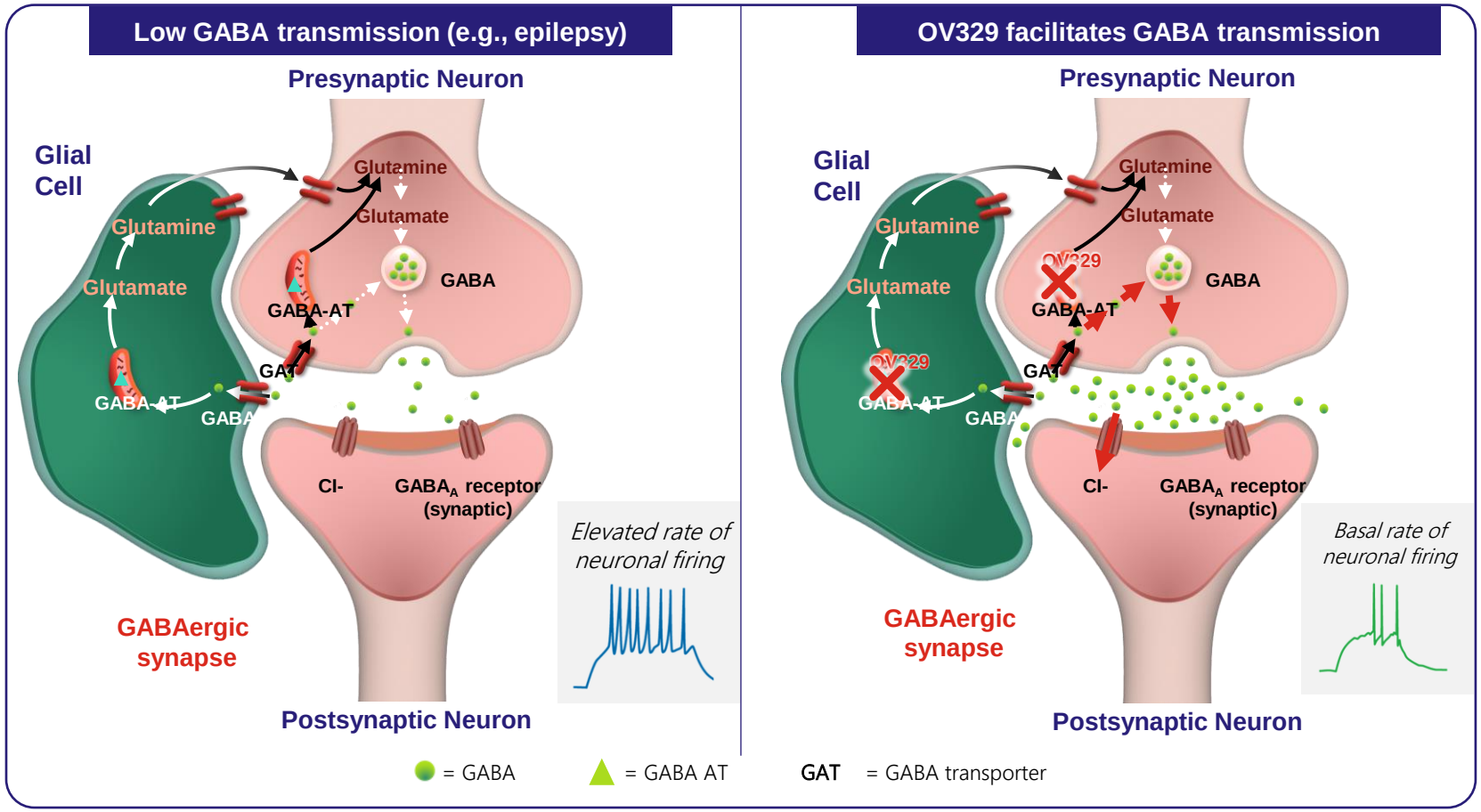
- More potent than vigabatrin in preclinical testing
- Potentially improved safety profile
- Anticipated lower dosing than vigabatrin will be needed

Vigabatrin



OV329





SOURCE:
[1]Juncosa, JI et al. *J. Am Chem. Soc.* 2018;140(6):2151-2164;
J Med Chem. 2012 Jan 26; 55(2): 567–575
J Am Chem Soc. 2018 Feb 14; 140(6): 2151–2164
J. Tsai, EILAT 2023 presentation

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Need for next-generation GABA-AT inhibitors

Sabril (vigabatrin) is only approved GABA-AT inhibitor

- Approved in 2009
- 1st line treatment for certain forms of infantile spasms, including seizures associated with tuberous sclerosis complex[1]
- Effective seizure reduction, but no therapeutic window[2]
- Post-approval, use of vigabatrin was associated with progressive visual field loss from retinal toxicity[3]
  - Deterred use
  - REMS

Significant market opportunity



Sabril peak sales in U.S.
(Not representative of global sales)[4]

Underserved patient populations

Prevalence: Tuberous sclerosis complex

~1 in 6,000 live births[5,6]



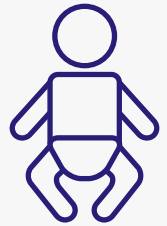
As many as 2 million people worldwide are believed to have disorder

~40,000 to 80,000 people in the US have TSC

Seizures are the most common neurological features of TSC (occur in ~85%)[7]

Prevalence: Infantile spasms
1.6-4.5 cases per 10,000 live births in the U.S.

~2,000 to 2,500 new cases in US per year[8]



[1] Pesaturo KA, Spooner LM, Belliveau P. Vigabatrin for infantile spasms. Pharmacotherapy. 2011 Mar;31(3):298-311. doi: 10.1592/phco.31.3.298. PMID: 21361740.
[2] Maguire et al., 2010; Epilepsia, 51(12):2423–2431, 2010
[3] BMJ 1997;314:180–181
[4] IMS sales of oral solution vigabatrin 2017

[5] Osborne, JP et al. *Lancet.* 2000;355(9216):1698 P;615:125
[6] Hong, CH et al. *Br J Dermatol.* 2016;174(6):1282-1289
[7] Kingswood, JC et al. *Orphanet J Rare Dis.* 2017;12(1):2
[8] Wheless, JW et al. *BMC Pediatr.* 2012;12:108;

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Six preclinical models reaffirm OV329 seizure reduction activity, including resistant seizure models[1]

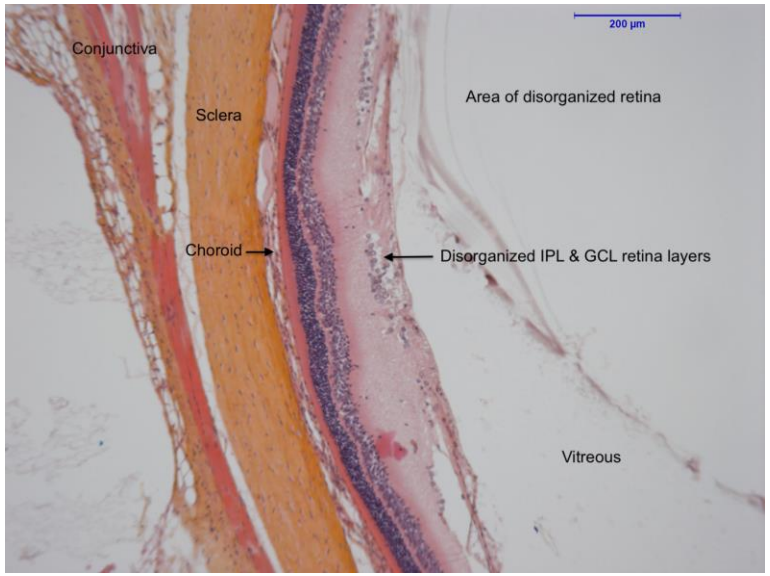
	6 Hz Electrical Stimulation	Maximal Electroshock (MES)	i.v. Pentylenetetrazol (ivPTZ)	NMDA-Induced Infantile Spasm Model	Audiogenic Seizure	Amygdala Kindled	Corneal Kindled	Intrahippocampal Kainate Model of Mesial-Temporal Lobe Epilepsy (MTLE)
Injury Model	Acute/seizure	Acute/seizure	Acute/seizure	Acute/seizure	Acute	Chronic/epilepsy	Chronic/epilepsy	Chronic/epilepsy
Clinical Correlate	Acute focal to bilateral tonic-clonic seizure	Generalized tonic-clonic seizure	Nonconvulsive seizures (eg absence, myoclonic)	Infantile spasms	Generalized seizures	Chronic focal to bilateral tonic-clonic seizure/ Pharmacoresistant seizures	Chronic focal to bilateral tonic-clonic seizure	Mesial temporal lobe epilepsy/ Pharmacoresistant seizures
Species	Mouse	Mouse	Rat	Mouse	Mouse	Rat	Mouse	Mouse
Dosing	Acute (0.01, 0.1, 0.3, 1 mg/kg/day, p.o.)	Acute (1, 3, 10, 30 mg/kg, p.o.)	Acute (5, 20, 40 mg/kg i.p.)	Acute (0.0025, 0.01, 0.1, 1 mg/kg, p.o.)	Acute (0.01, 0.05, 0.1 mg/kg, p.o.)	Acute (30, 40 mg/kg, i.p.)	Acute (1, 3, 10, 20, 30, 40, 60 mg/kg, p.o.)	Acute, single dose (0.01, 0.1, 1, 10 mg/kg, p.o.; 10 mg/kg, i.p.) Subacute (8 days q.d.) 0.3, 1.0 and 3.0 mg/kg/day (p.o.)
Activity	—	—	+	+	+	+	+	+

1. Ovid data on file

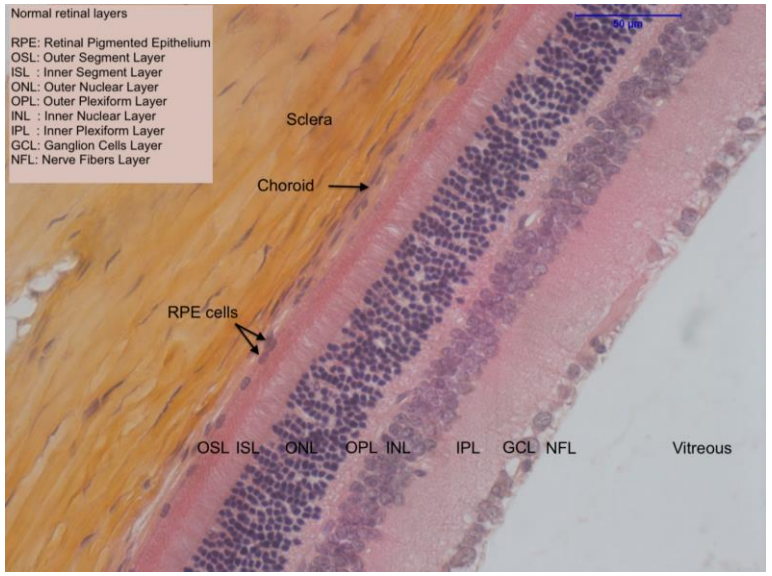
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No ocular effects seen following chronic exposure with OV329 (3 mg/kg)

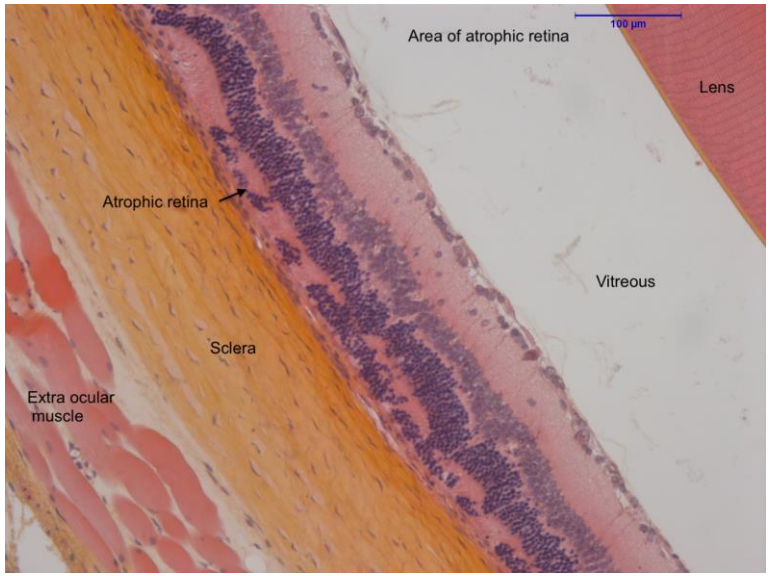
Vehicle



OV329 3.0 mg/kg



Vigabatrin 300 mg/kg



No ocular effects seen in 3 mg/kg OV329, q.d. and vehicle groups in rats at Day 45

Ocular effects seen in more than half of rats treated with Vigabatrin (300 mg/kg)

OVID, *Data on file*

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Active Phase 1 study

Design
Single (Part 1) and multiple (Part 2) ascending dose studies gated by cohort

Conducted at Duke University, School of Medicine

Healthy volunteers (6 active; 2 placebo)
8 volunteers per cohort

Target engagement measured by magnetic resonance spectrometry (MRS)
Levels of target engagement, as measured by MRS, have been correlated to therapeutic effect in prior GABA-AT inhibitors.[1, 2, 3]

Safety, tolerability and pharmacokinetic characterization of single and multiple doses of OV329

1. Petroff OA, Rothman DL, Behar KL, Collins TL, Mattson RH. Human brain GABA levels rise rapidly after initiation of vigabatrin therapy. Neurology. 1996 Dec;47(6):1567-71. doi: 10.1212/wnl.47.6.1567. PMID: 8960747.
2. Petroff OA, Rothman DL, Behar KL, Mattson RH. Human brain GABA levels rise after initiation of vigabatrin therapy but fail to rise further with increasing dose. Neurology. 1996 May;46(5):1459-63. doi: 10.1212/wnl.46.5.1459. PMID: 8628502.
3. Prescot AP, Miller SR, Ingenito G, Huber RS, Kondo DG, Renshaw PF. In Vivo Detection of CPP-115 Target Engagement in Human Brain. Neuropsychopharmacology. 2018 Feb;43(3):646-654. doi: 10.1038/npp.2017.156. Epub 2017 Jul 25. PMID: 28741622; PMCID: PMC5770752.

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OVERVIEW:

OV350 & KCC2 portfolio

Potential first-in-class direct activators of the KCC2 transporter

Innovative KCC2 program

- Consulting support by neuropharmacologist, Prof. Steve Moss
- Chemistry & lead identification conducted by AstraZeneca

Franchise in a program

- OV350 & compound library
- Individual compounds potentially suitable for:
  - IV – acute indications
  - Oral – chronic needs

Novel mechanism of action

- Only known direct KCC2 activator
- Measurable with biomarker (EEG high gamma power spectrum)[1]

Does not induce sedation[1]

in preclinical models

Broad therapeutic potential in rare & common populations including:

- Genetic epilepsies
- Acute epilepsies
- Neuropathic pain
- Behavioral & cognitive conditions

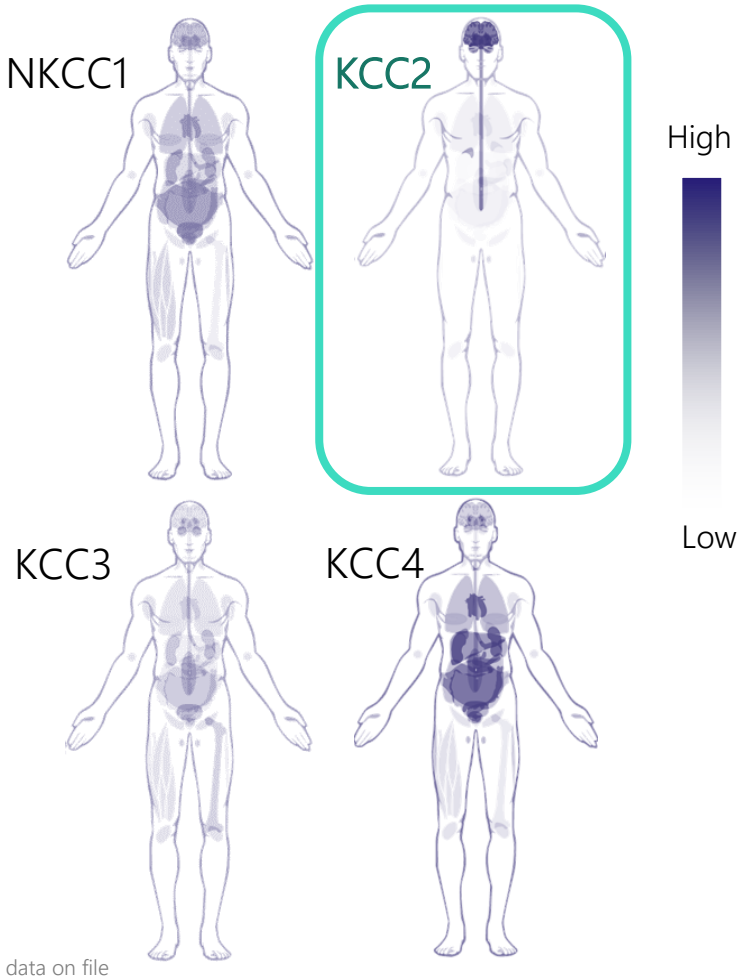
Preclinical POC demonstrated in-vivo & in-vitro in resistant seizures and other CNS indications[2]

[1]Maguire J. and Moss S.J. (in preparation)
[2] Ovid data on file.

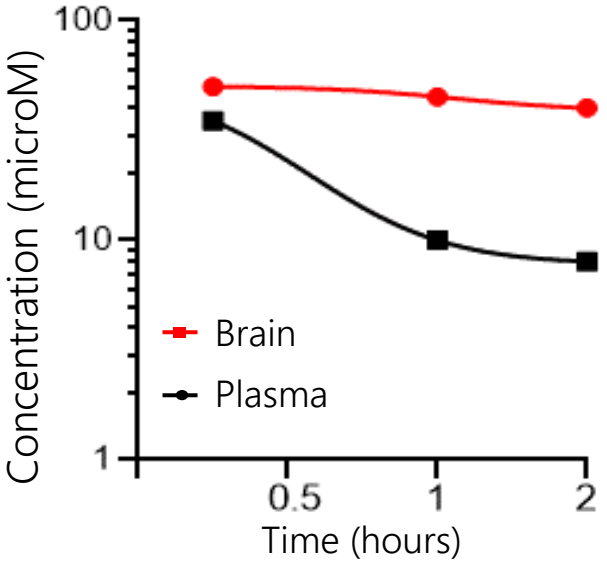
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OV350 preclinical models show rapid, stable accumulation in the brain with a translatable pharmacodynamic biomarker[1]

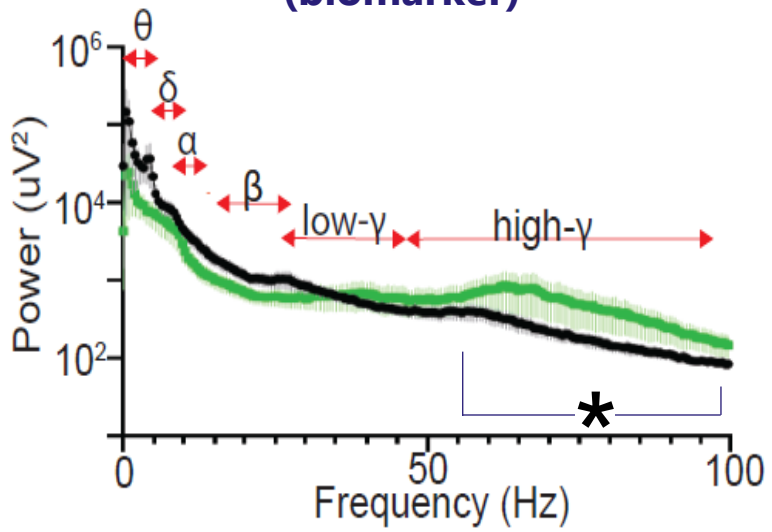
KCC2 is expressed exclusively in neurons, unlike other K/Cl co-transporters



OV350 rapidly accumulates in rodent brain via IV/IP dosing



OV350 induces a shift in EEG high gamma power spectrum (biomarker)



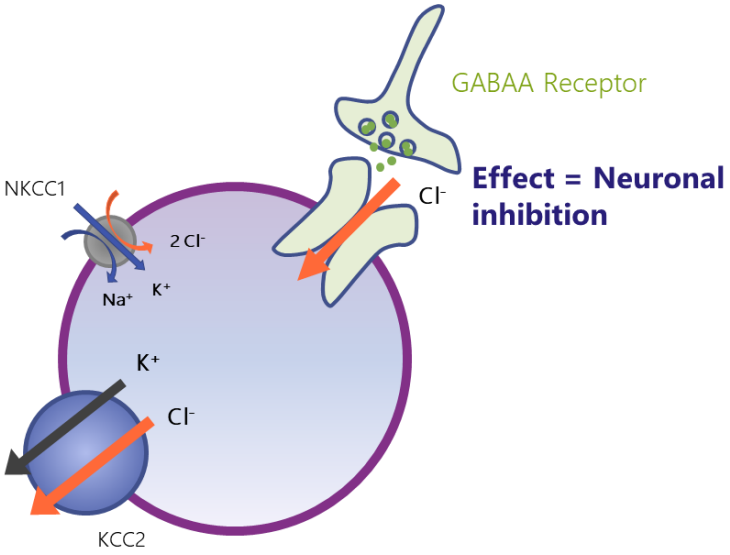
- OV350 in-vivo pharmacokinetics shows high micromolar accumulation in the brain within minutes
- Highly translatable EEG pharmacodynamic biomarker confirmed in healthy animals[1]

1. Ovid data on file

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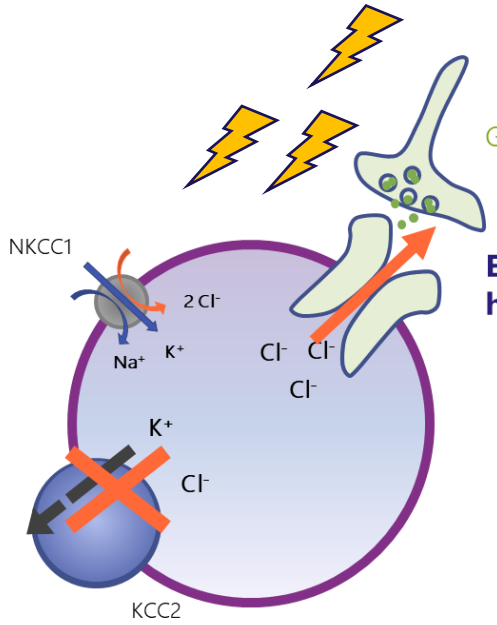
KCC2 transporter is central to regulating neuronal inhibition, potentially reducing seizures[1]

Healthy Neuron



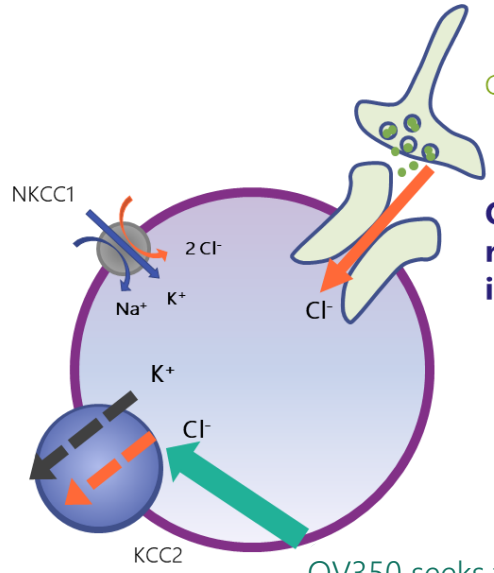
Effect = Neuronal inhibition

Epileptic Neuron



Effect = Neuronal hyperexcitability

Potential Effect of OV350



OV350 thought to return neuron to inhibitory state

OV350 seeks to directly activate the KCC2 transporter to improve chloride extrusion, thereby reversing neuronal hyperexcitability that produces seizures

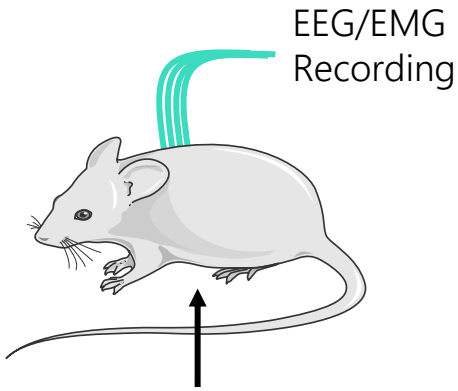
[1] Illustrations adapted from publication by Phan Q. Duy, Miao He, Zhigang He & Kristopher T. Kahle (2020) Preclinical insights into therapeutic targeting of KCC2 for disorders of neuronal hyperexcitability, Expert Opinion on Therapeutic Targets, 24:7, 629-637, DOI: 10.1080/14728222.2020.1762174

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In-vivo studies demonstrate mechanistic proof of concept

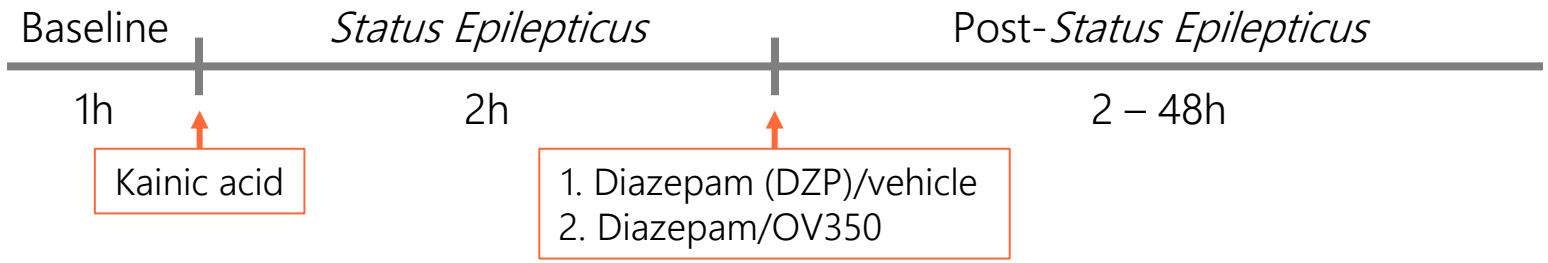
OV350 restores the efficacy of diazepam to terminate "refractory" *Status Epilepticus* in preclinical study

Adult Mouse

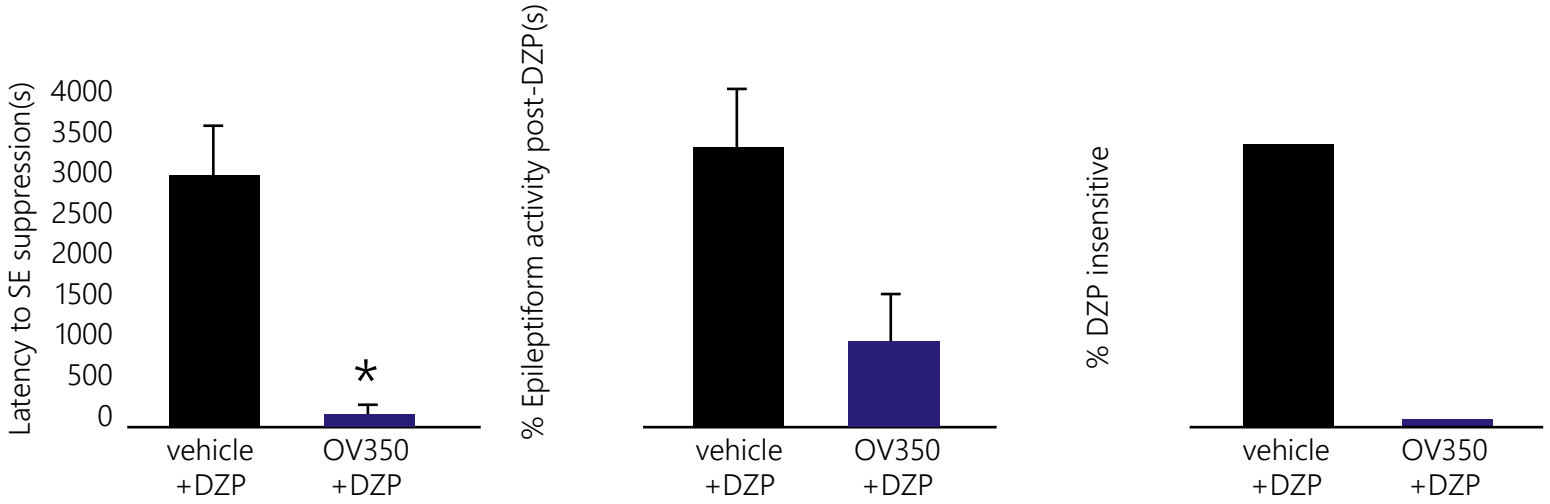


- Potentiating KCC2 activity observed to be well tolerated in-vivo
- Unlike other anti-convulsants, OV350 appears to not induce sedation

Experimental design



Post-treatment EEG analysis



*p<0.05 by academic lab t-test

Source: Maguire J. and Moss S.J. (in preparation)

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Creating value through business development

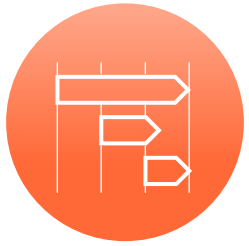
Capital from soticlestat licensing deal, coupled with expertise and access, allows for pursuit of successive disciplined and targeted transactions

Transaction goals

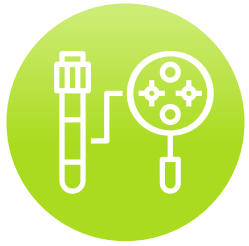
Leverage institutional epilepsy expertise



Complement and enhance current pipeline



Seek clinical-stage anti-seizure assets & programs



Conducted by a team with a track record of transformative transactions
100+ transactions completed by management team

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Investment highlights

+ Strong balance sheet

$137.9M — in cash, cash equivalents and marketable securities[1]

70.4M — shares of common stock outstanding[2]

Current cash runway into 2025

Potential for a non-dilutive capital stream from Takeda for years to follow

+ Veteran team

with a track record of developing and commercializing blockbuster medicines

+ Differentiated epilepsy franchise

- 3 small molecule programs (1 out-licensed to Takeda)
- Potential 1st-in-class or best-in-class medicines
- Novel, complementary mechanisms of action for the potential treatment of epilepsy & seizures
- Significant unmet need

+ Potential upcoming milestones

- Phase 3 data from SKYWAY study in Lennox-Gastaut syndrome (conducted by Takeda)
- Phase 3 data from SKYLINE study in Dravet syndrome (conducted by Takeda)
- Phase 1 results for OV329 assessing target engagement, safety & pharmacokinetics
- Anticipated submission of IND for OV350
- Series of potential regional regulatory filings for soticlestat (conducted by Takeda)

1 As of 9/30/22
2 As of 9/30/22, on an as if converted basis

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Ovid™ Therapeutics

Conquering epilepsies & brain disorders with courageous science















Ovid Therapeutics

Thank you.