Actinogen Medical AGM

Business Overview

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28th November 2018

Actinogen Medical

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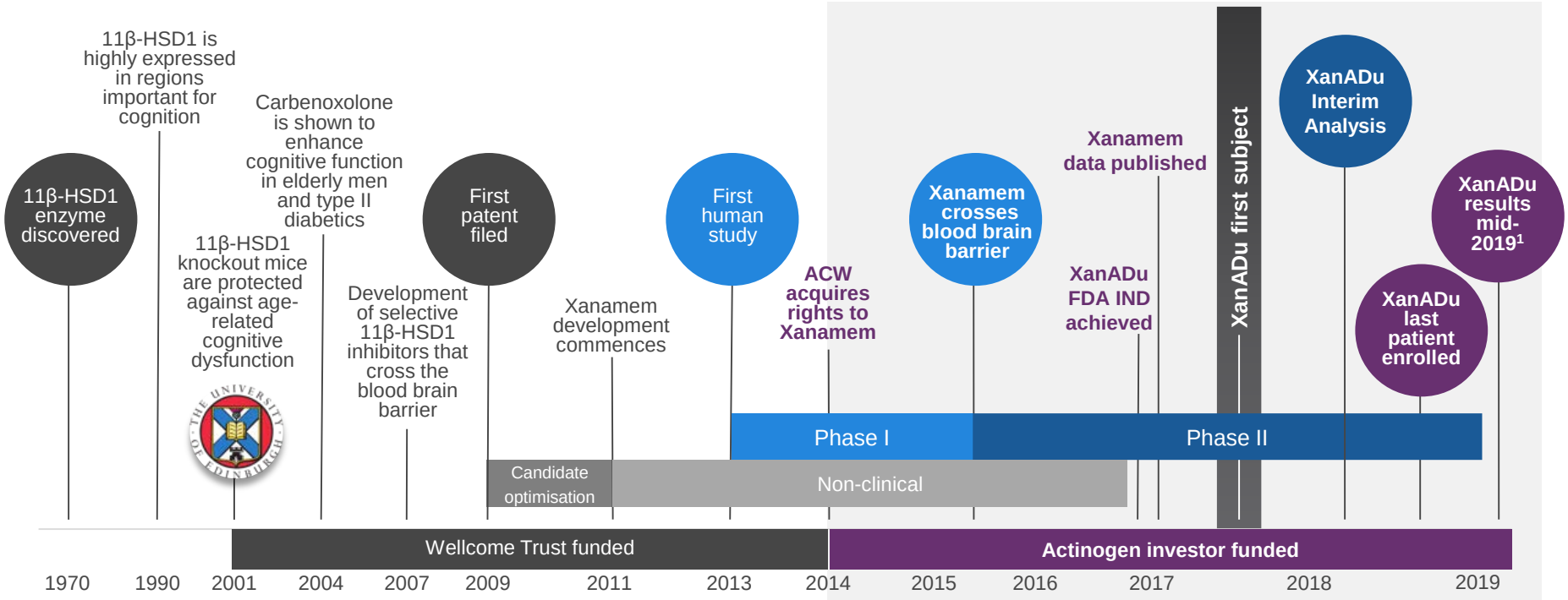
2018 Highlights

Actinogen‘s journey

Xanamem is underpinned by significant R&D investment and clinical progress over the last 15 years



1. Estimated timing of key milestones

2018 Highlights

XanADu

- **Enrolment completed**
- **Primary and secondary endpoints inform further development**
- **Positive safety interim analysis**

Building beyond XanADu

- Fully funded to complete XanADu and other Xanamem studies
- Xanamem Clinical Advisory Board and Scientific Advisory Board provide experienced leadership

Partnering

- ACW “Partner Ready” and ongoing partner outreach
- All major patents granted out to at least 2031
- Significant Big Pharma interest

Total of 186 patients with mild Alzheimer’s disease enrolled into XanADu with results on track for 2Q CY2019

1. Fully enrolled 26 November 2018 into XanADu, Phase II clinical trial of Xanamem. Study registered on Clinicaltrials.gov: NCT02727699

Xanamem Phase II clinical trial

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Double-blind, randomised, placebo-controlled study to assess the efficacy and safety of Xanamem in subjects with mild Alzheimer's disease[1]

Xanamem treatment course
12 weeks

186 patients with mild Alzheimer's disease (enrolment complete)[2]

10mg daily
Xanamem for 12 weeks (vs. placebo)

Trial conducted at 25 sites in
AUS, USA and UK

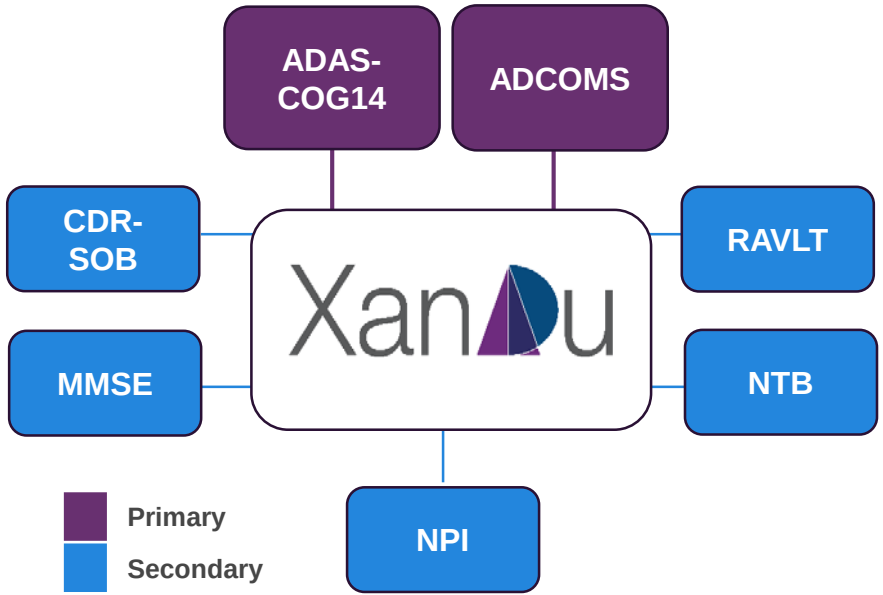
Fully funded study, fully enrolled with results due in 2Q CY2019

1. Study registered on Clinicaltrials.gov: NCT02727699
2. Fully enrolled 26 November 2018

XanADu Endpoints

XanADu's primary and secondary endpoints are the standard cognitive outcome measures used in Alzheimer's disease research globally

XanADu: primary and secondary endpoints[1]



Endpoints inform further development

XanADu endpoints are standard and validated assessments used in Alzheimer's disease research globally

While overlapping in many areas, each endpoint measures different discrete domains of cognition, and function in some.

XanADu is designed to identify the cognitive domains most sensitive to Xanamem's potential efficacy. Results will inform future development

1. ADAS-COG14: Alzheimer's Disease Assessment Scales – Cognitive Subscale Score (version 14); ADCOMs: AD COMposite Scores (composite data derived from ADAS-COG14, CDR-SOB and MMSE); CDR-SOB: Clinical Dementia Rating Scale – Sum of Boxes; RAVLT: Rey Auditory Verbal Learning Test; MMSE: Mini-Mental Status Examination; NTB: Neuropsychological Test Batteries; NPI: Neuropsychiatric Inventory

XanADu Interim analysis

Positive recommendations from the DSMB[1] reflect confidence in the safety of the drug and the design of the XanADu study. Supports the broader development of Xanamem

First DSMB review (23 May 2018)

- Evaluation of 50 patients' safety and efficacy data reviewed by an independent DSMB[2]
- **Recommendation by DSMB to continue XanADu without modification**

Second DSMB review (22 August 2018)

- Evaluation of 125 patients' safety data
- **Reaffirmed continuation of XanADu without modification**

Third DSMB review

- Expected to be completed in early CY2019

XanADu

Positive DSMB recommendations underpin the XanADu study and further development of Xanamem in other indications

1. DSMB: Data Safety Monitoring Board
2. Evaluable patients to have completed the study – note: an additional 37 patients' safety data was also included in the analysis (data was from patients still ongoing in the study)

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XanADu

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- Positive safety interim analysis

Building beyond XanADu

- **Fully funded to complete XanADu and other Xanamem studies**
- **Xanamem Clinical Advisory Board and Scientific Advisory Board provide experienced leadership**

Partnering

- ACW “Partner Ready” and ongoing partner outreach
- All major patents granted out to at least 2031
- Significant Big Pharma interest

Underpinned by substantial institutional investment – supported by leading clinicians and Xanamem discovery team

Substantial Institutional investment in Actinogen*

Recognises potential and endorses strategy

Positive interim analysis catalyses significant $15M investment through Placement

Leading investors enter register:

- USA specialist biotech investor **Biotechnology Value Fund L.P.**
- Australian institutions **Platinum Investments Management** and **Australian Ethical Investment**

Strong endorsement - Placement price represents a **13.4% premium** to the 5-day VWAP

BVF cornerstones Placement - largest shareholder with a **19.97% holding**

Funding to advance the development plan through additional Xanamem studies.

* Announced 23 May 2018

Additional value-adding Xanamem studies

Actinogen is focused on completing nine key additional studies to enhance the Xanamem data set, which can also be potentially leveraged into other indications

Target occupancy study

Aims to accurately demonstrate the effect different doses of Xanamem has on inhibiting the 11β-HSD1 enzyme In the human brain and to optimise Xanamem dosing

Currently underway with **results expected in 2Q CY2019**

XanaHES

Higher dose safety study

To expand the safety data-set for Xanamem and explore potential for higher doses of the drug to be used in Alzheimer's and other indications

XanaHES study initiated with **initial results expected in 2Q CY2019**

Further safety / toxicology studies

To allow for longer treatment periods, as routinely required by global regulatory authorities in the development of any drug

Additional studies initiated with **results expected in 6-12 months**

Actinogen is fully funded to complete these additional Xanamem studies

Advisory Boards

World's premier academics involved in the development of Xanamem and as a novel treatment for Alzheimer's disease

Xanamem Clinical Advisory Board

Positions Xanamem at the forefront of Alzheimer's drug development

Prof. Craig Ritchie *Chair*

THE UNIVERSITY of EDINBURGH

Prof. Colin Masters *AO*

THE UNIVERSITY OF MELBOURNE

The Royal Melbourne Hospital

THE FLOREY INSTITUTE OF NEUROSCIENCE & MENTAL HEALTH

Prof. Jeffrey Cummings

Cleveland Clinic

Scientific Advisory Board

Combining deep understanding of cortisol, 11β-HSD1 and drug discovery

Prof. Jonathan Seckl

THE UNIVERSITY of EDINBURGH

Prof. Brian Walker

Newcastle University

Prof. Scott Webster

THE UNIVERSITY of EDINBURGH

2018 Highlights

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Building beyond XanADu

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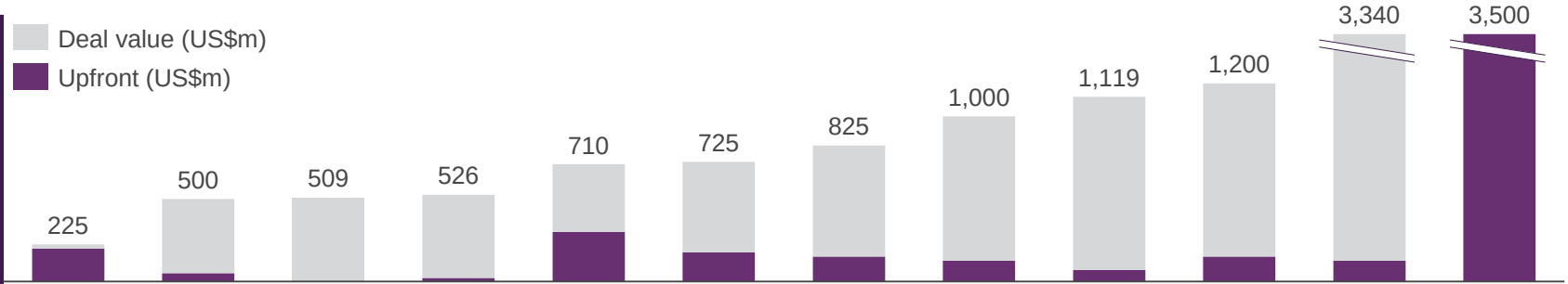
Partnering

- **Ongoing outreach program and business development**
- **Significant Big Pharma interest**
- **All major patents granted out to at least 2031**

Actinogen is well positioned to unlock further value

Big Pharma interest

Global Big Pharma demonstrating strong M&A interest in acquiring or partnering with companies and licensing novel mechanism of action assets with Alzheimer's disease as the lead/key indication

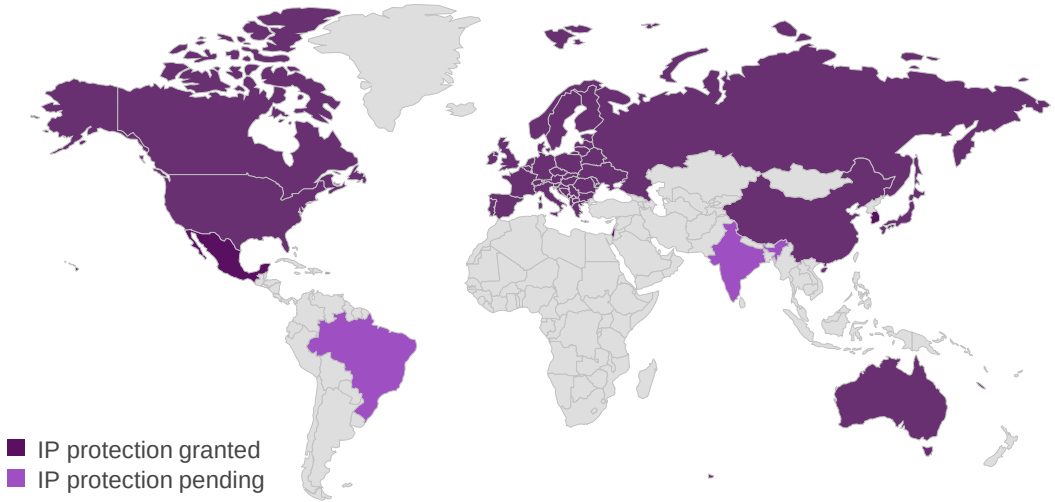


Bidder / Licensee	abbvie	Lilly	janssen	MERCK	Biogen	PIERIAN	Otsuka	Allergan	abbvie	Takeda	Allergan	Otsuka
Target / Licensor	ALECTOR	AstraZeneca	AC Immune	Bionomics	Bristol-Myers Squibb	Bristol-Myers Squibb	Lundbeck	CHASE Pharmaceuticals Corporation	Voyager Therapeutics	DENALI	HEPTARES therapeutics	AVANIR
Year	2017	2014	2015	2014	2017	2014	2013	2016	2018	2018	2016	2014
Deal type	Partnership	Partnership	Partnership	Partnership	Licence	Asset	Partnership	Acquisition	Partnership	Partnership	License	Acquisition
Candidate	Immuno-neurology platform	AZD3293	ACI-35	BNC-375	BMS-986168	IPN007	LU AE58054	CPC-201	Gene Therapy platform	Brain-penetrant ATV	Three M1/M4 agonists	AVP-786
Phase	Pre-clinical	I	I	Pre-clinical	I	Pre-clinical	II	II	Pre-clinical	Pre-clinical	I	III
Novel MoA (not anti-amyloid)	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓

IP protection

Actinogen maintains a broad granted composition of matter patent estate, extending to at least 2031, with key patents granted in all major target markets

Geographic patent overview



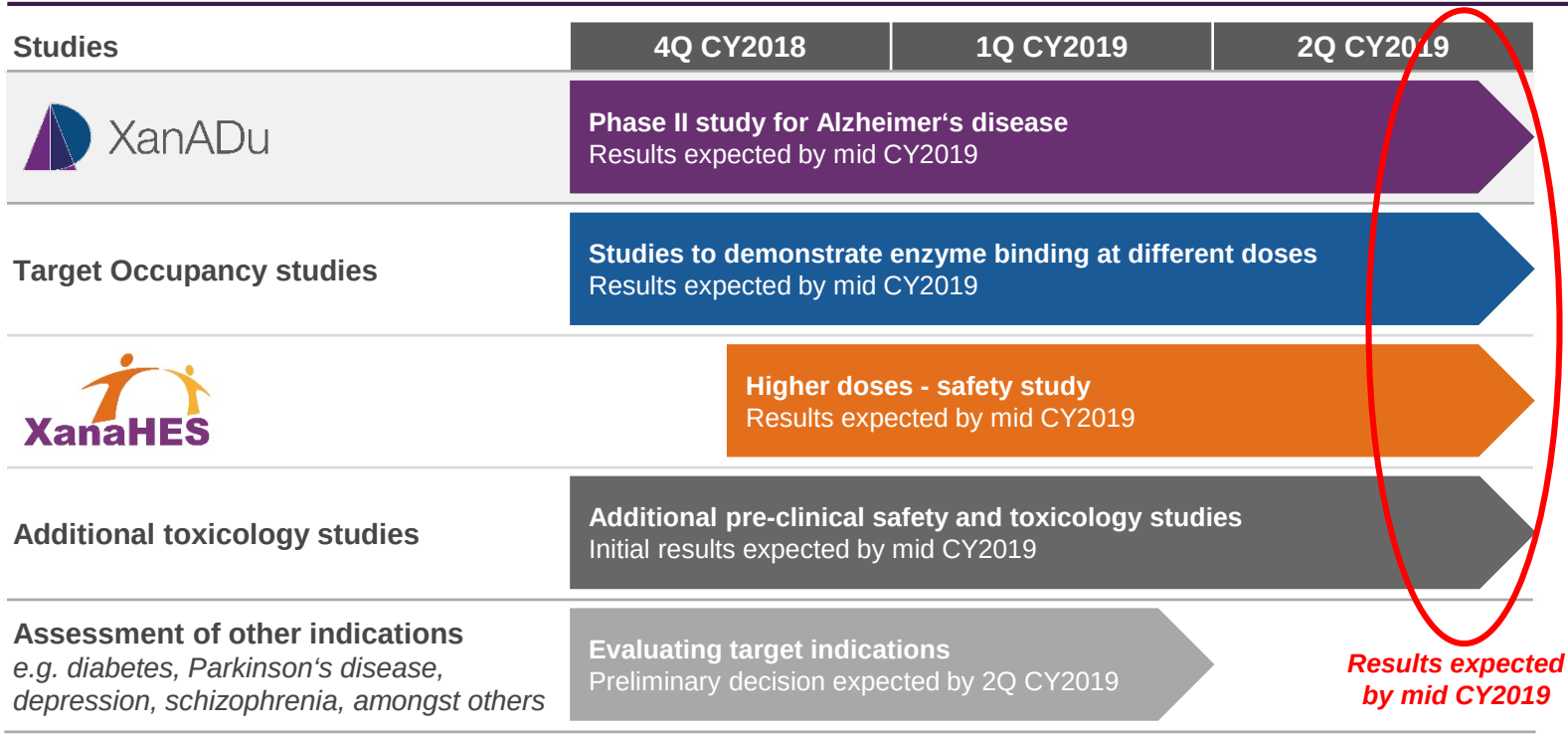
- Actinogen's patent portfolio **covers a broad range of neurological and metabolic diseases** including Alzheimer's disease
- Xanamem **patents granted in key markets** that account for over 90% of the global Alzheimer's market
- **Actinogen's patent portfolio extends to at least 2031**

>90% of the global Alzheimer's disease market

2019 Outlook

Clinical development and milestones

Well progressed Phase II clinical trial (XanADu) underpinned by additional value-adding studies and an exciting Xanamem pipeline for other potential indications



Proactive strategic business development

Continued strategic engagement with prospective development and commercial partners in the lead up to XanADu results

Progressing collaboration and commercial discussions with prospective big pharma partners, and presenting to, and educating the scientific community

Planned H1 CY2019
Partnering and Investment Conference Attendance

JP Morgan Healthcare Conference | January, San Francisco

SACHS Neuroscience | January, San Francisco | Oral Presentation

BIO-Europe Spring 2019 | March, Vienna

BIO 2019 | June, Philadelphia

13TH ANNUAL INTERNATIONAL PARTNERING CONFERENCE
BIO-EUROPE SPRING®

SACHS ASSOCIATES 2 NEUROSCIENCE INNOVATION FORUM
For BD&L and Investment in Therapeutics and Technology
6th Jan 2019 | Marines' Memorial Club, SF | USA

Planned CY2019
Scientific Conference Attendance

AD/PD 2019 | March, Lisbon

AAIC 2019 | July, Los Angeles

CTAD 2019 | December, San Diego

Market dynamics of Alzheimer's disease

Presents a compelling commercial opportunity for Actinogen to target initially

Substantial target market with significant upside[1]

Cortisol-high, cognition normal	Subjective memory decline	Cognitive and functional decline fulfilling dementia		
At-risk	Prodromal	Mild	Moderate	Severe
~25.0m (50% over 65 yrs)	**~4.0m**	**~1.5m**	~1.7m	~2.5m

Upside potential for earlier use *Key focus*

>US$7.5bn

Target annual peak sales (mild AD)[2]

Underpinned by favourable market dynamics

- ✓ Targeting **large addressable** markets (US, EU5, JP)
- ✓ All **currently approved drugs are symptomatic treatments** (that do not affect disease progression) **providing limited benefit**
- ✓ Treatment **prices are robust** (despite generic competition) – with users paying for modest clinical efficacy

US branded products (gross price)

US$10/day

US$8/day

US$18/day

Source: Drugs.com, Biogen, Roche, Datamonitor, Alzheimer's Association

1. Target market statistics based on the current US treatment landscape
2. Base case annual peak sales assumes: (1) Launch: US 2024, EU5, JP and ROW 2025; (2) Penetration: 30% of mild AD market in 5 years (i.e. ~470,000 in the US); (3) Pricing: US – US$19/day (gross), ROW: 50% of US price

Comparison of Alzheimer's disease treatments

Actinogen's novel treatment for Alzheimer's disease is clearly differentiated and may be used in combination with existing cognitive enhancers and potential anti-amyloid drugs (currently in development)

Overview

	Xanamem	Cognitive enhancers	Anti-amyloid drugs
Status	**In development**	In market[1]	In development
Mechanism of action	**Targets cortisol**	AChE[2] inhibitors, NMDA[2] receptor antagonist	Anti-amyloid
Administration	**Oral (small molecule)**	Oral (small molecule)	Injectable IV / SC[3] (biologics)
Evidence of disease modification	✓[4]	✗	✓
Duration of effect (>8 months)	✓[4]	?	✓
Potential to treat 'at risk' patients	✓	✗	✓
Applicable to other cognitive disorders	✓	✗	✗
No SAEs identified	✓	✗	✗
No biomarker required	✓	✓	✗
Low cost of goods	✓	✓	✗

1. Analysis excludes other cognitive enhancers currently in development
2. AChE: acetylcholinesterase; NMDA: N-methyl-D-aspartate
3. IV: intravenous; SC: subcutaneous
4. Evidence of disease modification and duration based on animal model studies

Xanamem may support potential combination therapy, with existing treatments and other drugs currently in development, to improve patient outcomes

- Approved cognitive enhancers have different mechanism of action and varying degrees of benefit and duration
- Despite promising data, anti-amyloid therapy has high costs, compliance challenges and requires IV / SC administration

Significant headwinds for BACE inhibitor development

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Significant opportunity for Xanamen development, with recent study data indicating that anti-amyloid may not be efficacious as initially expected

Overview[1]

- Results indicate **potent anti-amyloid activity has not translated to substantial cognitive benefit**
- T**rending / actual cognitive worsening was observed** across multiple compounds

Company	Compound (Phase) *Status*	Population	CSF Aβ lowering range	Cognition comments
MERCK	Verubecestat (III) *Stopped for futility*	Mild moderate	60% - 80%	**Early:** Trend for cognitive worsening **Overall:** No difference
		Prodromal	60% - 80%	**Early:** Cognitive worsening **Overall:** Cognitive worsening
Lilly AstraZeneca	Lanabecestat (III) *Stopped for futility*	Prodromal – mild	55% - 75%	**Early:** Trend for cognitive worsening **Overall:** Data not locked
		Mild	55% - 75%	
Johnson&Johnson	Atabecestat (III) *Stopped for hepatic safety*	Cognitively unimpaired	50% - 82%	**Early:** Trend for cognitive worsening - Cognitive worsening **Overall:** Dosing discontinued
Lilly	LY3202626 (II) *Stopped for futility*	Mild dementia	70% - 90%	**Early:** Trend for cognitive worsening - Equivocal **Overall:** Dosing discontinued
Eisai Biogen	Elenbecestat (III) *Ongoing*	Mild moderate	~60%	**Early:** Trends for improvement **Overall:** General trends for improvement
AMGEN NOVARTIS	CNP520 (II/III) *Ongoing*	Cognitively unimpaired	20% - 90%	**Early:** Not applicable **Overall:** No difference

1. Information presented at CTAD (Clinical Trials on Alzheimer's Disease) Conference held in Barcelona in October 2018

XanADu, Xanamem and Cortisol

Video featuring the Xanamem Clinical Advisory Board - October 2018, Barcelona

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XanADu, Xanamem and Cortisol.
October 2018, Barcelona

Featuring:
– Dr Bill Ketelbey, CEO Actinogen Medical

Xanamem Clinical Advisory Board Members:
– Professor Craig Ritchie
– Professor Colin Masters AO
– Professor Prof Jeffrey Cummings

https://actinogen.com.au/video

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