ASX ANNOUNCEMENT

Cognitive improvement demonstrated with Xanamem™

- **Statistically significant results demonstrate cognitive improvement in healthy elderly subjects dosed with 20mg Xanamem daily in the XanaHES dose escalation study**
- **Statistically significant reduction in serum cortisol following treatment with Xanamem 20mg daily**
- **Xanamem 20mg daily continues to exhibit a good safety profile with no serious adverse events observed**
- **Results significantly enhance the Xanamem dataset and help shape Actinogen's drug development strategy for the treatment of Alzheimer's disease and other neurological and metabolic diseases associated with cognitive impairment**
- **Company to host a Conference Call on October 1st, 2019 (today) at 10:30am (AEST)**

Sydney 1 October 2019: Actinogen Medical ASX: ACW ('ACW' or 'the Company') is delighted to announce results from the XanaHES *(Xanamem in Healthy Elderly Subjects)* trial. The results demonstrate a significant improvement in cognition in trial participants dosed with Xanamem 20mg daily for 12 weeks, compared to placebo. This is the first time Xanamem has shown such a clear, statistically significant cognitive improvement in humans.

These breakthrough results reinforce the hypothesis and science underpinning the discovery and development of Xanamem - that lowering persistently raised cortisol levels in the brain is expected to positively enhance cognition.

Results from the study also showed that Xanamem, at a dose of 20mg daily, significantly ($p<0.001$) reduced serum cortisol levels in the trial participants over the study period. Furthermore, Xanamem 20mg daily exhibited a good safety profile over the 12 weeks of treatment, with no reports of serious adverse events.

Professor Michael Woodward from the Austin Health in Melbourne and one of the leading investigators in the XanADu trial said*: "It is just so pleasing and encouraging to see this positive efficacy data for Xanamem, following the disappointment of the XanADu trial. There have been so many past failures with the development of Alzheimer's drugs, so these promising results offer renewed hope for a treatment breakthrough for this devastating disease".*

As previously announced, the XanADu trial in mild Alzheimer's patients showed that Xanamem 10mg daily was safe and altered the cortisol pathway but did not demonstrate an improvement in cognition.

The XanaHES trial was primarily designed as a placebo-controlled study to investigate the safety of 20mg Xanamem in healthy elderly subjects, but also included an exploratory assessment of cognition to evaluate the cognitive efficacy of Xanamem, using the industry standard Cogstate Cognitive Test Battery. The Cogstate Battery evaluated six domains of cognition, with the goal of broadly investigating whether 20mg Xanamem daily could positively influence cognition. Results from this trial show cognitive improvement in three of the six domains investigated after 12 weeks treatment (see table 1 below for more detail):

- One Back Test: evaluating working memory - highly statistically significant ($p<0.01$ with an effect size of 0.83)
- Identification Test: evaluating visual attention – statistically significant ($p=0.05$ with an effect size of 0.67)

- Detection Test: evaluating psychomotor function – trend to statistical significance (p=0.09 with an effect size of 0.76).

Effect size is a quantitative measure of the magnitude of a result indicating that treatment with 20mg Xanamem daily has a potentially important impact on these cognitive domains. See table 1 below for more details.

These results demonstrate an encouraging clinical efficacy signal in cognitive domains that are core to cognitive evaluation across many diseases.

Actinogen Medical Clinical Advisory Board member, Professor Jeff Cummings from the Cleveland Clinic in the USA commented*: "These results from the XanaHES study provide Actinogen with evidence of Xanamem's ability to enhance cognition and inhibit cortisol production. Considering the broad array of medical conditions presenting with cognitive impairment and an associated raised cortisol, these promising results provide many opportunities for the ongoing development of the drug."*

Enhancement of cognition in the XanaHES trial supports Xanamem's potential for the treatment of Alzheimer's disease and other conditions associated with cognitive impairment, including mood disorders like bipolar disorder, and schizophrenia

Actinogen CEO Dr Bill Ketelbey said: *"These are the results we have been looking for. They are hugely important for the development of Xanamem and for the potential for Xanamem to treat Alzheimer's disease and other conditions associated with cognitive impairment"*

"As we gather and analyse more data from XanaHES and the other ongoing studies, we are building a much clearer picture of Xanamem's pharmacology, potential efficacy, safety, and mechanism of action; all of which will aid substantially in planning the future clinical development and commercialisation strategy for the drug."

"We look forward to sharing Actinogen's future development plans for Xanamem once they have been reviewed alongside these very pleasing results."

Table 1: Results summary

COGNITIVE EVALUATION (Test)	P value	Effect Size: Cohen's d			
		Week 2	Week 4	Week 8	Week 12
WORKING MEMORY (One Back Test)	<0.01*	0.64#	0.78#	0.64#	0.83Δ
VISUAL ATTENTION (Identification Test)	0.05*	0.19	0.67#	0.62#	0.67#
PSYCHOMOTOR FUNCTION (Detection Test)	0.09	0.47	0.65#	1.12Δ	0.76#

Notes: * statistical significance achieved;
effect size >0.5 (medium treatment effect);
Δ effect size >0.8 (large treatment effect)

Conference Call at 10.30am today

The Company will host a **conference call at 10:30am (AEST) on Tuesday 1st October 2019 (today).**

The presentation that will be referred to in the call, is attached to this announcement.

The Company invites participants to ask questions during the call. In addition, interested parties may submit questions prior to the call to info@actinogen.com.au.

Participants are encouraged to pre-register for the call here:

https://s1.c-conf.com/DiamondPass/Actinogen-invite.html

You will receive a PIN and diary note for fast-track entry to the call. Alternatively, participants may dial in at the scheduled time using the dial-in number below

Conference ID: 10002238

AUSTRALIA:	1800 870 643
ALTERNATIVE AUSTRALIAN NUMBER:	1800 809 971
OTHER INTERNATIONAL (METERED):	+61 7 3145 4010
SYDNEY:	02 9007 3187
NEW ZEALAND:	0800 4530 55
AUCKLAND:	0992 9168 7
CHRISTCHURCH:	0397 4263 2
WELLINGTON:	0497 4773 8
CHINA:	4001 2006 59
FRANCE:	0800 9814 98
GERMANY:	0800 1827 617
HONG KONG:	8009 66806
JAPAN:	0053 1161 281
SINGAPORE:	8001 0127 85
SOUTH KOREA:	0079 8142 0632 75
UK:	0800 0518 245
USA/CANADA:	1855 8811 339
CHICAGO:	1815 3732 080
LOS ANGELES:	1909 2354 020
NEW YORK:	1914 2023 258

ENDS

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About Actinogen Medical

Actinogen Medical (ASX: ACW) is an ASX-listed biotechnology company focused on innovative approaches to treating cognitive decline that occurs in chronic neurological and metabolic diseases. Actinogen Medical is developing its lead compound Xanamem, as a promising new therapy for Alzheimer's disease, a condition with multibillion-dollar market potential and material human impact. In the US alone, the cost of managing Alzheimer's disease is estimated to be US$250bn and is projected to increase to US$2tn by 2050, outstripping the treatment costs of all other diseases. Alzheimer's disease is now the leading cause of death in the UK and second only to ischaemic heart disease in Australia. In addition, Actinogen is currently planning an expanded clinical development program for Xanamem in cognitive impairment in mood disorders and schizophrenia. In the US alone, the collective economic costs of mood disorders and schizophrenia are estimated to exceed $550bn, with the burden increasing every year. The cognitive dysfunction associated with these conditions is significantly debilitating for affected patients, with a substantial unmet medical need for novel, improved treatments.

About Xanamem™

Xanamem's novel mechanism of action sets it apart from other Alzheimer's treatments. Xanamem is brain penetrant and works by blocking the excess production of cortisol - the stress hormone – through the inhibition of the 11β-HSD1 enzyme. There is a strong association between chronic stress and excess cortisol that leads to changes in the brain affecting memory. The 11β-HSD1 enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain associated with cognitive impairment in neurological diseases, including Alzheimer's disease, mood disorders and schizophrenia.

About XanADu

XanADu is a Phase II double-blind, 12-week, randomised, placebo-controlled study to assess the safety, tolerability and efficacy of 10mg Xanamem once daily in subjects with mild dementia due to Alzheimer's disease. XanADu has fully enrolled 186 patients from 25 research sites across Australia, the UK and the USA. The trial is registered on www.clinicaltrials.gov with the identifier: NCT02727699, where more details on the trial can be found, including the study design, patient eligibility criteria and the locations of the study sites.

About XanaHES

XanaHES is a Phase I, randomised, single blinded, central reader blinded, placebo-controlled, dose escalation study to assess the safety and tolerability of Xanamem™ 20mg & 30mg once daily in healthy elderly volunteers. The XanaHES trial randomised 42 healthy elderly participants to receive either 20mg Xanamem daily (30 subjects) or placebo daily (12 subjects) for 12 weeks. Changes in cognitive performance from baseline to end-of-treatment will be measured as an exploratory efficacy outcome.

Actinogen Medical encourages all current investors to go paperless by registering their details with the designated registry service provider, Link Market Services.

Investor Conference Call

A novel approach to treating cognitive impairment and Alzheimer's disease

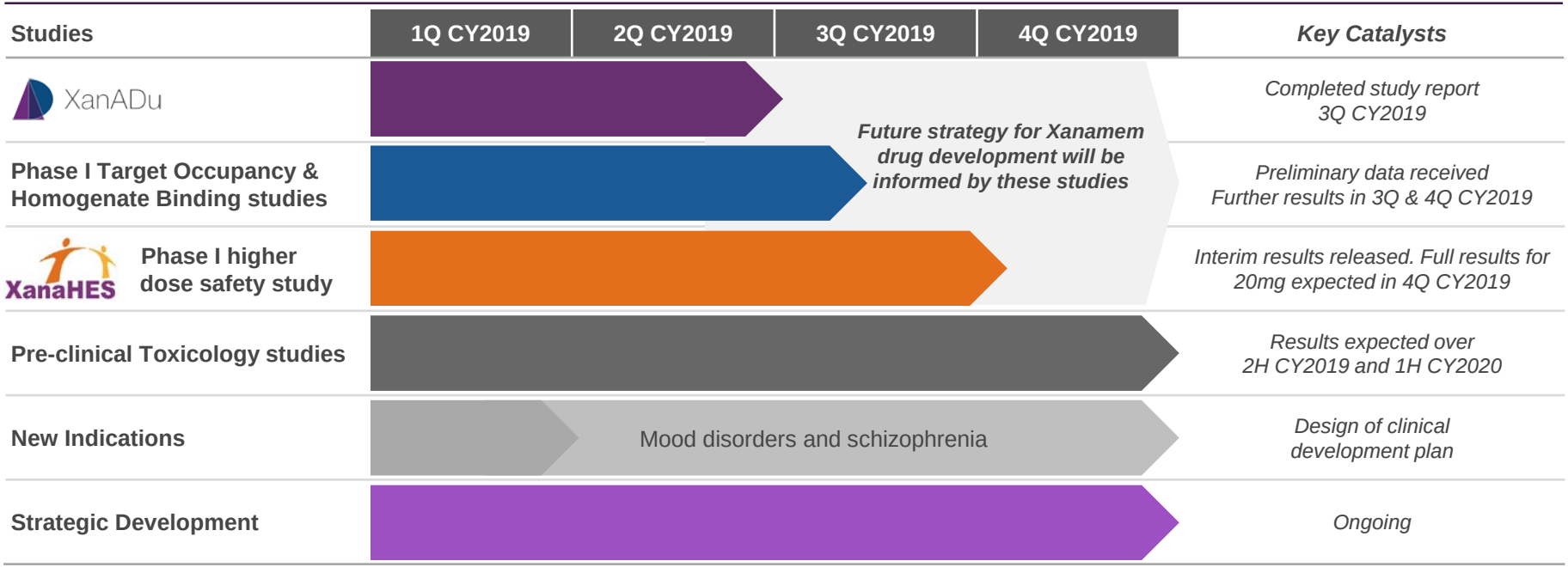
Dr. Bill Ketelbey: CEO & MD

October 2019

Actinogen Medical

Development Pipeline and Upcoming Catalysts

Multiple studies currently underway with significant upcoming milestones in the near term



Actinogen is fully funded to complete all current studies

Comprehensive Xanamem Clinical Development Program

The ongoing comprehensive review of the data and results from XanADu and the additional studies will inform the optimal clinical development path

XanADu

Multiple endpoints and sub analyses will allow insight into Xanamem's potential and where it is most effective

Phase I Target Occupancy, & Homogenate Binding Studies

Measures effects of different Xanamem doses on inhibiting the 11β-HSD1 enzyme in the brain

Totality of results assessed by Actinogen and expert Clinical Advisory Board

Key focus today

XanaHES

Assess safety and tolerability of higher doses (to allow higher doses in future trials), with an efficacy assessment included

Additional Toxicology Studies

Pre-clinical safety and toxicology studies to allow for longer treatment periods

The totality of results will inform further Xanamem development

Phase I clinical trial

Single blind placebo-controlled, dose escalation study to assess safety, tolerability and efficacy of Xanamem in healthy elderly subjects – full results expected in 4Q CY2019

12 weeks
Xanamem treatment course
Trial conducted at 1 site in Australia

42
Healthy elderly subjects
(no cognitive impairment)

20mg daily
Xanamem 30 subjects
Placebo 12 subjects

Cognition assessed
Through computerised efficacy tests
(Cogstate CTB[1])

Key objective to expand the Xanamem safety dataset and evaluate potential for higher dosage in future clinical trials

1.Cogstate Cognitive Test Battery

Cognitive Efficacy Signal Achieved

XanaHES included a cognition endpoint to evaluate the cognitive efficacy of Xanamem using the Cogstate Cognitive Test Battery which evaluated six domains. Cognitive improvement demonstrated in three domains

XanaHES 20mg Cogstate Cognitive Test Battery: p values and Cohen's d effect size

Cognitive Evaluation (Test)	p value			Treatment Effect Size: Cohen's d			
	All	Male	Female	Week 2	Week 4	Week 8	Week 12
Working Memory (One Back Test)	**<0.01***	**<0.01***	**0.03***	**0.64#**	**0.78#**	**0.64#**	**0.83Δ**
Visual Attention (Identification Test)	**0.05***	**0.04***	0.60	0.19	**0.67#**	**0.62#**	**0.67#**
Psychomotor Function (Detection Test)	**0.09**	0.94	0.13	0.47	**0.65#**	**1.12Δ**	**0.76#**
Paired Associate Learning (CPAL[1] Test)	0.21	0.34	0.49	**0.87Δ**	0.01	**0.66#**	0.08
Memory (CPAL[1] – Delayed Test)	0.50	0.55	0.21	0.34	0.23	0.06	0.48
Visual Learning (One Card Learning Test)	0.92	0.41	0.64	0.11	0.12	**0.60#**	0.19

Additional details on slide 5

Notes: * statistical significance achieved; # effect size >0.5 (moderate treatment effect); Δ effect size >0.8 (large treatment effect)

1: CPAL – Continuous Paired Associate Learning

Cognitive Efficacy Signal Achieved (cont'd)

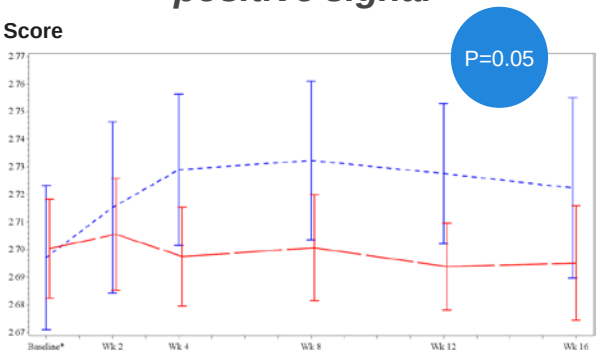
Breakthrough results demonstrated statistically significant cognitive efficacy signal in multiple cognition domains – based on Cogstate Cognitive Test Battery

Working memory (One Back Test)

Strongly statistically significant result

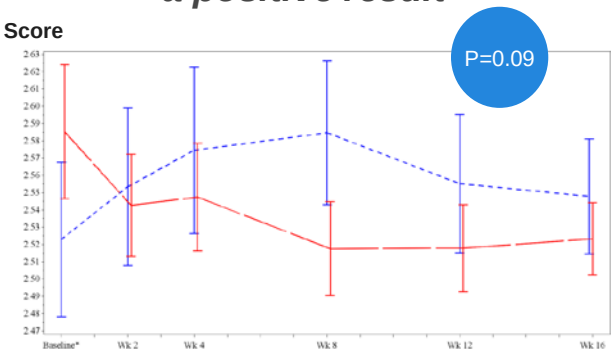
Visual attention (Identification Test)

Statistically positive signal



Psychomotor function (Detection Test)

Good trend to a positive result



Efficacy results of particular interest, reflecting high quality and consistent data in a small study population

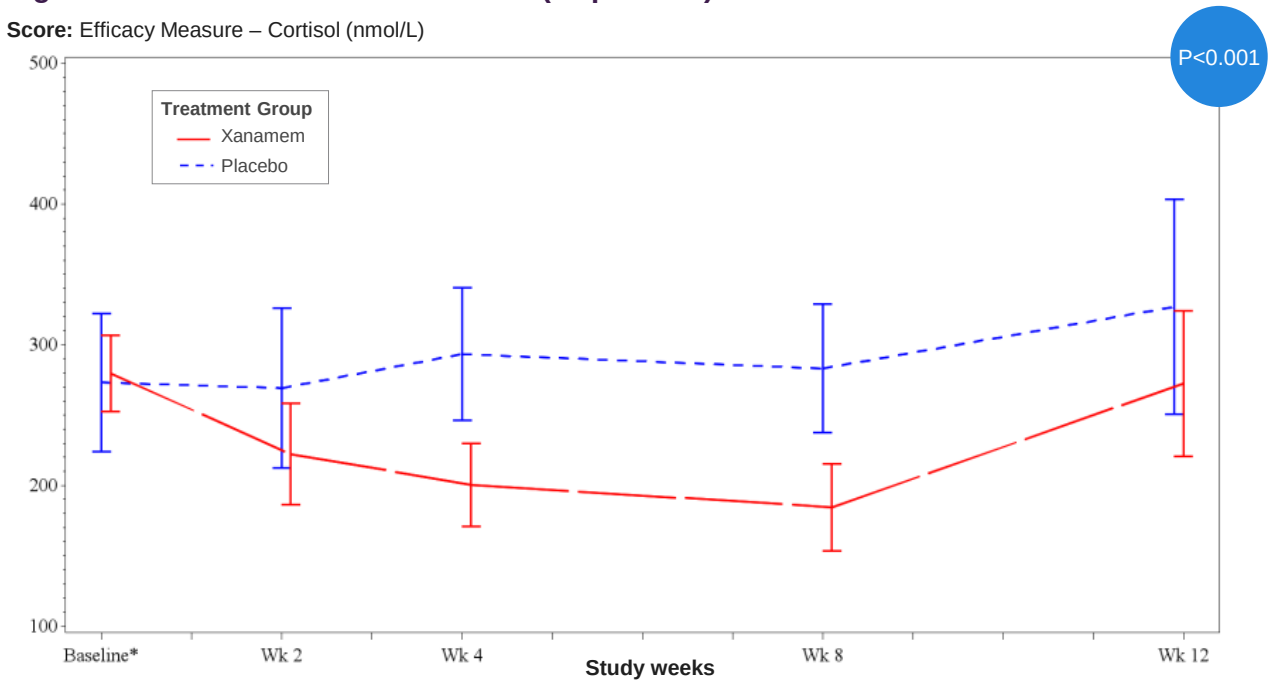
Baseline* Mean of Observed Data

Cortisol Levels Reduced with Acceptable Safety

Efficacy results complemented by the statistically significant reduction in serum cortisol observed in the trial

Significant reduction in cortisol levels (all patients)

Score: Efficacy Measure – Cortisol (nmol/L)



Baseline * Mean of Observed Data

Xanamem achieved an average decrease of 73.2 vs. placebo (p<0.001)

These breakthrough results support the cortisol hypothesis that lowering persistently raised cortisol levels in the brain is expected to positively enhance cognition

XanADu: Possible Reasons Behind XanADu results

Likely due to the recurrent challenges seen in Alzheimer's disease drug development

Conceptual model of the disease

- Causality unknown; cortisol as a target is a hypothesis
- Diagnoses largely based on highly subjective tools

Stage of disease

- Wrong patient population ("too early" or "too late")
- High heterogeneity as to the real biological drivers behind each individual's disease state

Outcome/endpoint measures

- Absence of valid biomarkers
- Subjectivity of outcome assessments flawed

Patient recruitment and retention

- Overall patient population may have been too heterogeneous to generalise results

Xanamem

- Dose: too low or too high?
- Dosing regimen: may need bi-daily dosing?
- Treatment duration: may need to treat for longer?

Xanamem: Phase I Target Occupancy Study & Homogenate Binding Studies

To assist with confirming and optimising Xanamem dosing

Aim

To accurately demonstrate the effects different doses of Xanamem have on inhibiting the 11β-HSD1 enzyme in the human brain.

Phase I Target Occupancy studies

- Competitive binding, radio-labelled tracer PET imaging assay
- Subject cohorts tested with Xanamem at 5mg, 10mg, 20mg, and 30mg doses.
- Data available from 10-30mg dosing cohorts

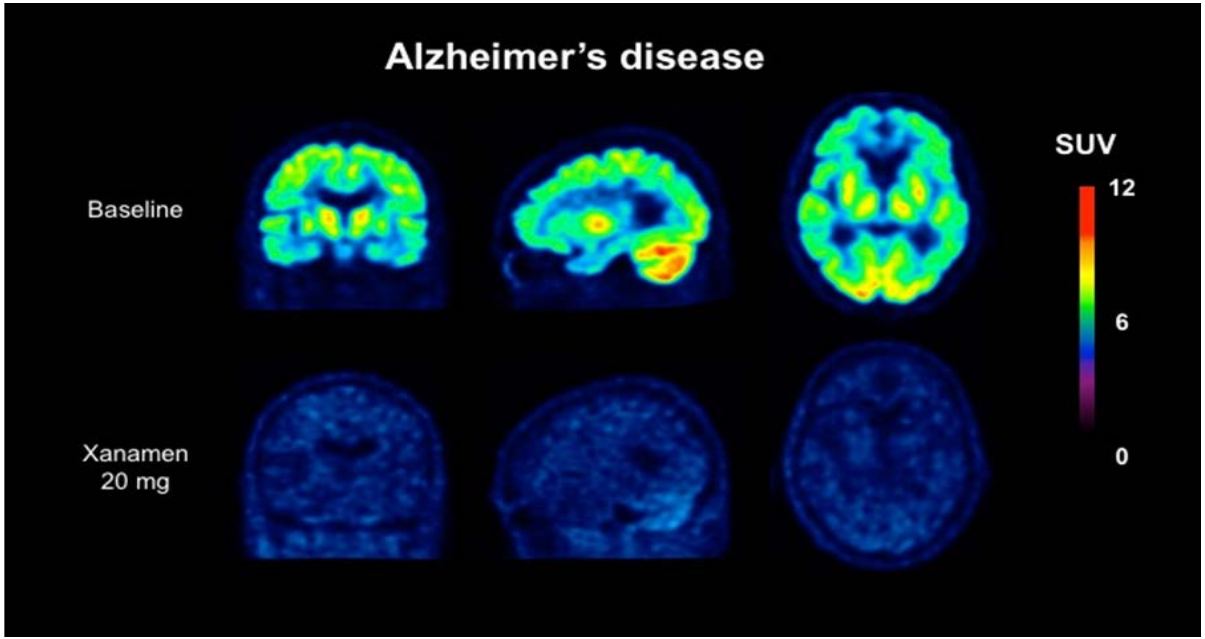
In vitro Homogenate Binding Studies

- Enzyme occupancy competition studies, saturation binding studies, and enzyme activity assays in rat and human brain sections (ongoing)
- To correlate enzyme occupancy and enzyme activity at incremental doses of Xanamem

Key studies to help interpret XanADu results and support future clinical development strategy

Target Occupancy Study: Preliminary Results

Phase I target occupancy study demonstrates that 10-30mg Xanamem dosed for seven days significantly occupies neuronal 11β-HSD1 throughout the brain



50% to 85% occupancy, dependent upon brain region, dosage and study subject

Further study data available in 4Q CY2019

Additional ongoing cohorts at 5mg Xanamem and 10mg with delayed PET imaging

Phase I Target Occupancy supports Xanamem as a potent, orally bioavailable and brain-penetrant 11β-HSD1 inhibitor

Long-Term Safety and Toxicology Studies

Aim

Evaluate safety and toxicology in rodent (six months) and dog (nine months) studies in preparation for longer term clinical studies

- Studies **required by all regulators - FDA**
- Will allow future **clinical studies beyond 12 weeks**
- Studies **ongoing**
- **No substantive safety issues** observed to date

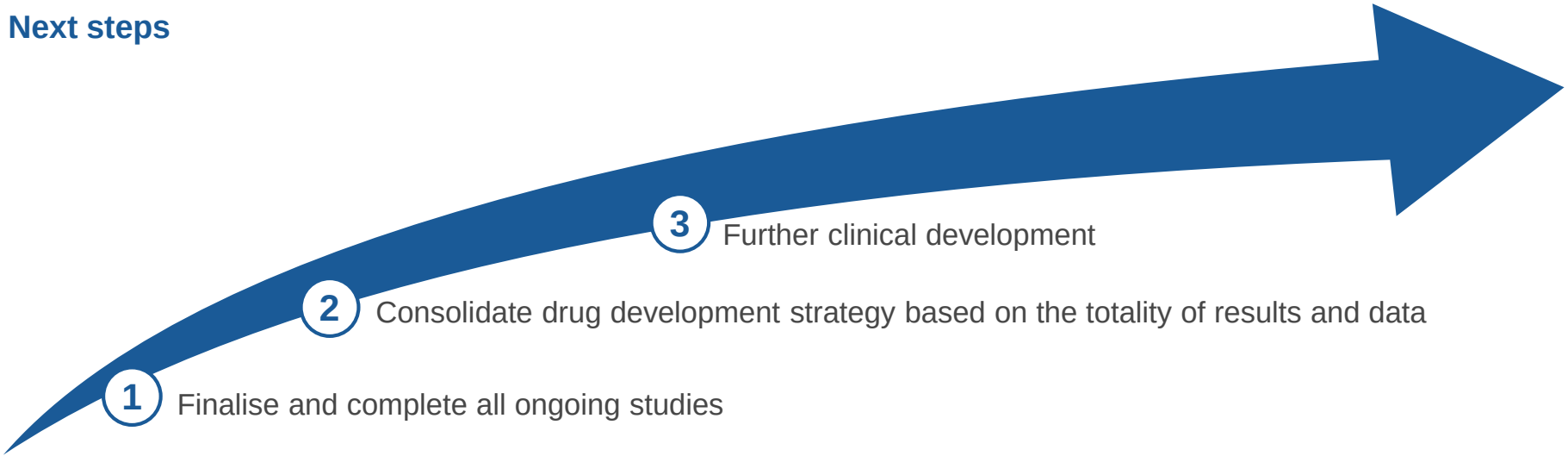
Key study to support future clinical development strategy

Strategic direction

Key ongoing Xanamem studies are providing data and results in the near term, with the totality of the information from all studies to inform Actinogen's strategic review for future clinical development

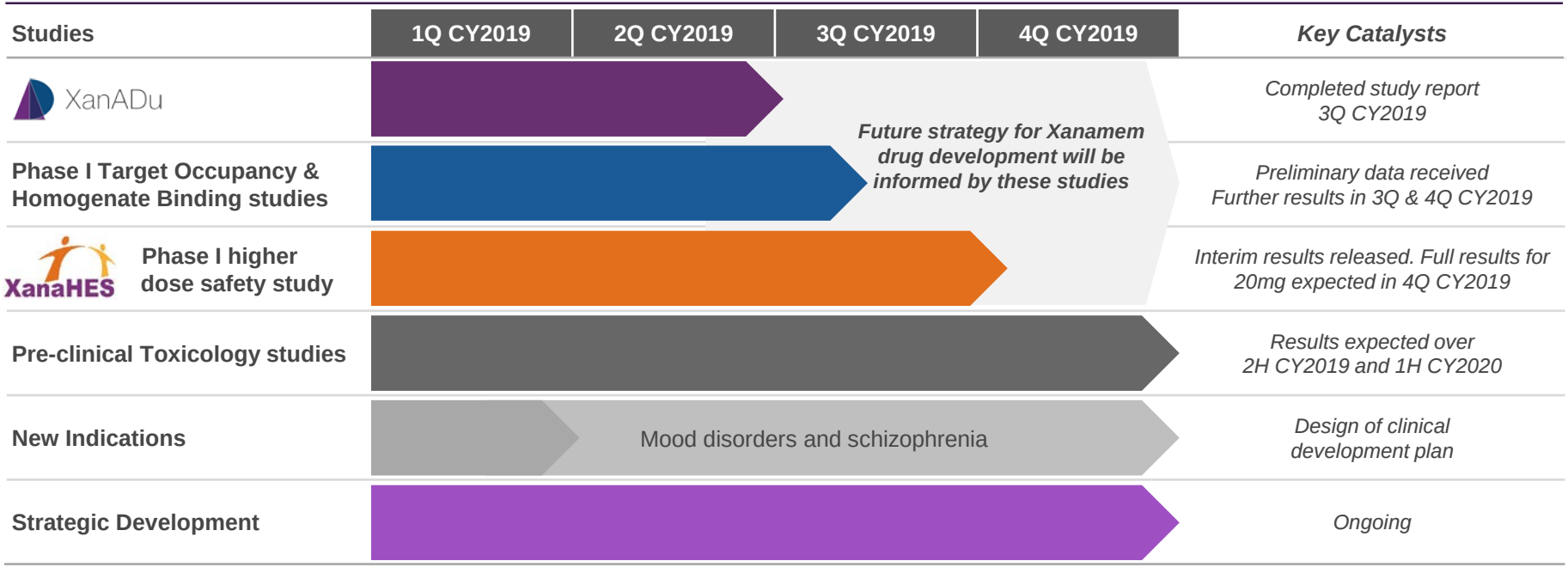
Xanamem has demonstrated to be an **efficacious**, **safe, brain penetrant, orally available, selective 11β –HSD1 inhibitor** with significant pharmacodynamic effects on cortisol

Next steps



Development Pipeline and Upcoming Catalysts

Multiple studies currently underway with significant upcoming milestones in the near term



Actinogen is fully funded to complete all current studies

Q&A Session

Appendix:
Background information

Summary

Actinogen is developing innovative treatments for cognitive impairment associated with neurological and metabolic diseases with an initial focus on Alzheimer‘s disease

Xanamem - lead compound

Differentiated with a novel mechanism of action
First-in-class, brain penetrant, orally active, small molecule, inhibitor of 11β-HSD1 enzyme
Xanamem mechanism of action validated by independent research on the cortisol hypothesis

Targeted strategic market focus

Initially focused on developing a treatment for Alzheimer's disease
Addressable market worth >US$7.5bn with unmet needs and potential upside.
Target indication underpinned by efficacy results from animal model studies.
Mood disorders and schizophrenia identified as additional opportunities

Clinical stage asset

Advanced clinical stage program assessing Xanamem in Alzheimer’s disease and cognitive impairment in other neurological conditions. Complementary higher dose and target occupancy phase I studies will inform future development

Potential value upside

Totality of existing studies will inform further development and commercial potential of Xanamem

De-risked opportunity

Fully funded programs
Initial data from additional studies indicate brain penetration, good target occupancy and safety profile

Experienced leadership

Board and Management with significant drug development and corporate experience, supported by key opinion leaders and Xanamem discovery team

Xanamem

A novel drug designed to inhibit cortisol production in the brain, with the potential to treat cognitive impairment

Well researched
>15 years of R&D completed

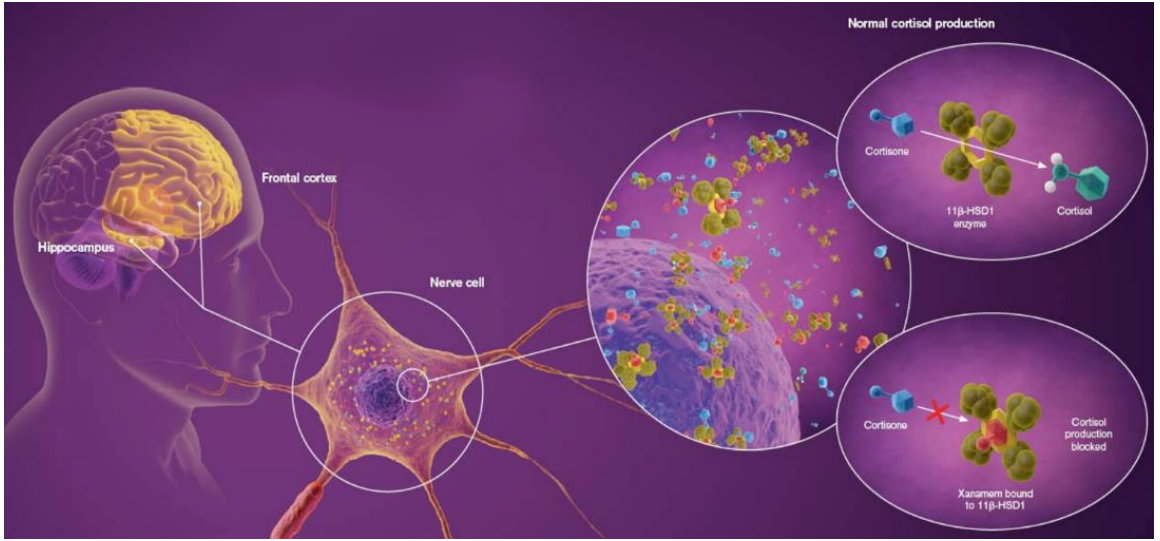
Well tolerated
Dosed >200 patients with acceptable clinical safety, toxicity & PK / PD[1] profile

Well protected
Composition of matter IP coverage, patents granted in all major markets

Validated in Alzheimer's disease
Symptomatic and disease modifying effects (in vivo) and demonstrated effect of cortisol hypothesis (in humans)

Potential in other diseases
Secondary focus on cognitive impairment in mood disorders and schizophrenia

Differentiated mechanism of action:
Highly selective 11βHSD1 inhibitor in the brain which reduces excess cortisol production



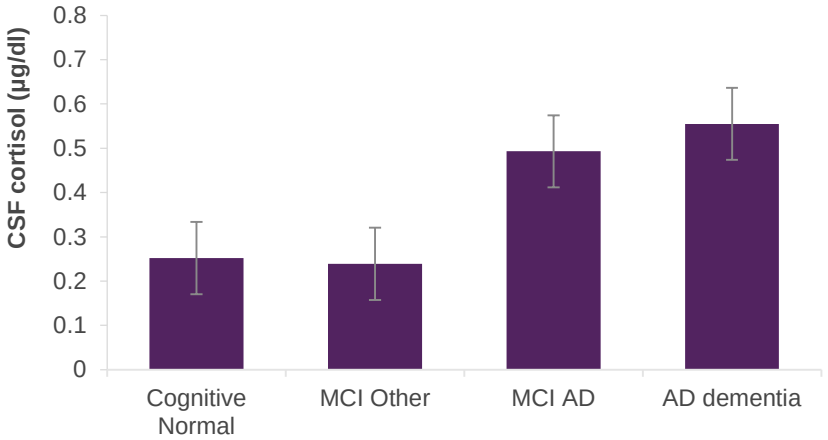
Xanamem is a novel, first-in-class, potent, orally bioavailable and brain-penetrant 11β-HSD1 inhibitor

1. PK / PD: pharmacokinetic / pharmacodynamic

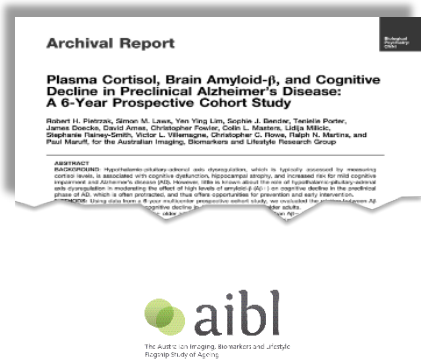
Alzheimer‘s strategic focus underpinned by medical research

A growing body of medical literature supports the association between cortisol and Alzheimer‘s disease

Raised cortisol associated with Alzheimer’s disease[1]



Supported by growing body of medical literature


Archival Report

Plasma Cortisol, Brain Amyloid-β, and Cognitive Decline in Preclinical Alzheimer's Disease: A 6-Year Prospective Cohort Study

Robert H. Pietrzak, Simon M. Laws, Yen Ying Lim, Sophie J. Bender, Tenielle Porter, James Doecke, David Ames, Christopher Fowler, Colin L. Masters, Lidija Milicic, Stephanie Rainey-Smith, Victor L. Villemagne, Christopher C. Rowe, Ralph N. Martins, and Paul Maruff, for the Australian Imaging, Biomarkers and Lifestyle Research Group

ABSTRACT

BACKGROUND

aibl

The Australian Imaging, Biomarkers and Lifestyle Flagship Study of Ageing

Many studies support the association between **cortisol and Alzheimer’s disease development and progression**[2]

A recent AIBL[3] study provided compelling evidence that elderly subjects with **higher plasma cortisol levels are at much greater risk of developing Alzheimer‘s disease**

This study[3] also demonstrated **that 50% of those aged 65+ have raised cortisol levels**

Research suggests that lowering cortisol levels may prevent the development / progression of Alzheimer’s disease

1. MCI: mild cognitive impairment; AD: Alzheimer’s Disease
2. Recent studies also support the association between cortisol and cognitive impairment associated with neuroendocrine dysfunction
3. Plasma Cortisol, Brain Amyloid-β, and Cognitive Decline in Preclinical Alzheimer’s Disease: a 6-Year Prospective Cohort Study. Pietrzak et al., 2017. Biological Psychiatry: Cognitive Neuroscience and Neuroimaging 2:45-52

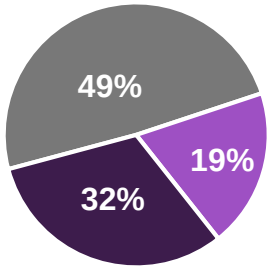
Corporate overview ASX:ACW

Actinogen is an ASX-listed biotech company focused on innovative approaches to treating cognitive impairment associated with neurological and metabolic diseases

Overview

- Actinogen is developing Xanamem, a novel therapy for Alzheimer's disease, mood disorders and schizophrenia, with significant market potential
- Xanamem - lead drug, designed to inhibit cortisol production in the brain, with the potential to treat cognitive impairment
- Actinogen has completed a Phase II double-blind, 12 week, randomised, placebo-controlled study of Xanamem in Alzheimer's disease (XanADu)

Key shareholding metrics



BVF Partners

Top 20 (excl. BVF Partners)

Remaining shareholders

Board of Directors

Dr. Geoff Brooke

Chairman

MBBS; MBA

- **30+ years experience** in the healthcare investment industry
- Founder and MD of Medvest Inc and GBS Venture Partners

Dr. Bill Ketelbey

CEO & MD

MBBCh; FFPM; MBA; GAICD

- **30+ years experience** in healthcare, biotech and pharmaceutical industries
- Formerly senior international roles at Pfizer and Director at Westmead Institute of Medical Research

Dr. George Morstyn

Non-executive director

MBBS; PhD; FRACP; MAICD

- **25+ years experience** in biotech investment and drug development
- Board member of Biomedvic, Cancer Therapeutics and Symbio; Former Senior VP and SMO at Amgen

Mr. Malcolm McComas

Non-executive director

BEc, LLB; FAICD; SF Fin

- **25+ years experience** in the financial services industry
- Chairman of Pharmaxis and Fitzroy River Corporation; formerly senior leadership roles in investment banking

Advisory Boards

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

Clinical Advisory Board (Alzheimer's disease)

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

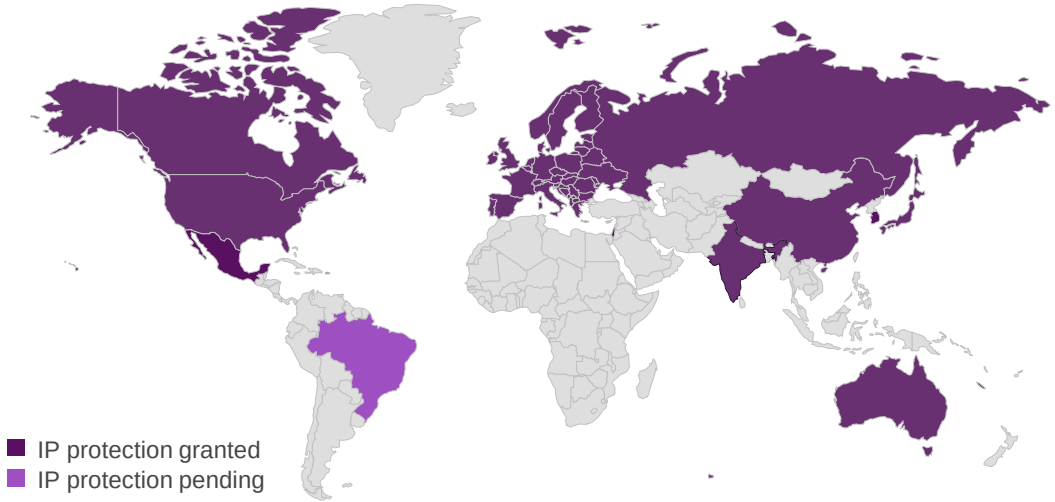
Prof. Scott Webster

THE UNIVERSITY of EDINBURGH

IP protection

Actinogen maintains a broad granted composition of matter patent estate, 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
- **Additional patents and patent extension being actively prosecuted**

>90% of the global Alzheimer's disease market

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

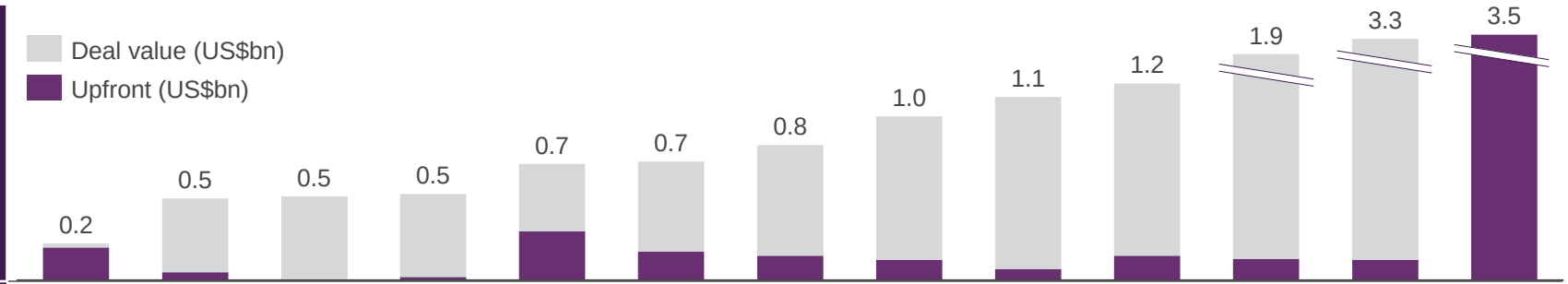
US$18/day

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 (US$12/day net), ROW: 50% of US price

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



Deal value (US$bn)	0.2	0.5	0.5	0.5	0.7	0.7	0.8	1.0	1.1	1.2	1.9	3.3	3.5
Bidder / Licensee	abbvie	Lilly	janssen	MERCK	Biogen	PIERIAN	Otsuka	Allergan	abbvie	Takeda	Lilly	Allergan	Otsuka
Target / Licensor	ALECTOR	AstraZeneca	AC Immune	Bionomics	Bristol-Myers Squibb	Bristol-Myers Squibb	Lundbeck	CHASE Pharmaceuticals Corporation	Voyager THERAPEUTICS	DENALI	AC Immune	HEPTARES therapeutics	AVANIR
Year	2017	2014	2015	2014	2017	2014	2013	2016	2018	2018	2018	2016	2014
Deal type	Partnership	Partnership	Partnership	Partnership	Licence	Asset	Partnership	Acquisition	Partnership	Partnership	License	License	Acquisition
Candidate	Immuno-neurology platform	AZD3293	ACI-35	BNC-375	BMS-986168	IPN007	LU AE58054	CPC-201	Gene Therapy platform	Brain-penetrant ATV	ACI-3024	Three M1/M4 agonists	AVP-786
Phase	Pre-clinical	I	I	Pre-clinical	I	Pre-clinical	II	II	Pre-clinical	Pre-clinical	Pre-clinical	I	III
Novel MoA (not anti-amyloid)	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

XanADu Phase II clinical trial

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

Largest AD global clinical trial run by an Australian biotech

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

XanADu: Phase II Clinical Trial Completed

Double-blind, randomised, placebo-controlled study to assess the efficacy and safety of Xanamem in subjects with mild Alzheimer's disease[1], with initial results announced 7th May 2019

XanADu initial results

- Efficacy end points were not achieved
- Potent pharmacodynamic modulation of cortisol-related hormones achieved
- Xanamem is well-tolerated with no safety concerns
- Sub-analyses of results currently underway

Possible reasons behind XanADu results

- Recurrent challenges seen in AD drug development
- Xanamem dose / study duration

Ongoing development

- Phase I **target occupancy** studies
- **XanaHES** dose escalation study
- Long-term animal **toxicology** studies
- New indications for future focus selected: mood disorders (such as **bipolar disorder**) and **schizophrenia**

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

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