

9 October 2020

ASX Announcement

ADALTA TO PRESENT AT BIO INVESTOR FORUM DIGITAL CONFERENCE

MELBOURNE Australia, 9 October 2020: AdAlta Limited (ASX:1AD), a clinical stage biopharmaceutical discovery and development company using i-body technology to address challenging drug targets advises that CEO and Managing Director, Dr Tim Oldham, will discuss the attached investor presentation at the BIO Investor Forum Digital Conference to be held virtually from 13-15 October 2020.

The BIO Investor Forum has become the premier event where biotech innovators can find investors and strategic partners to advance their company to the next stage in their business life cycle. The presentation will be available on demand throughout the conference and can also be found on the Company's website at: https://adalta.com.au/investors/presentations/

During the presentation, Dr Oldham provides a summary of recent events and updates on the Company's Phase I clinical trials of lead asset AD-214 being developed for Idiopathic Pulmonary Fibrosis and on the Company's collaboration with multinational company GE Healthcare.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
October 2020

Notes to Editors About AdAlta

AdAlta Limited is a clinical stage drug development company headquartered in Melbourne, Australia. The Company is using its proprietary i-body technology platform to solve challenging drug targeting problems and generate a promising new class of single domain antibody protein therapeutics with the potential to treat some of today's most challenging medical conditions. The i-body technology mimics the shape and stability of a unique and versatile antigen-binding domain that was discovered initially in sharks and then developed as a human protein. The result is a range of unique proteins capable of interacting with high selectivity, specificity and affinity with previously difficult to access targets such as G-protein coupled receptors (GPCRs) that are implicated in many serious diseases. i-bodies are the first fully human single domain antibody scaffold and the first based on the shark motif to reach clinical trials.

AdAlta is conducting Phase 1 clinical studies for its lead i-body candidate, AD-214. AD-214 is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases, for which current therapies are sub-optimal and there is a high unmet medical need.

The Company is also entering collaborative partnerships to advance the development of its i-body platform. It has an agreement with GE Healthcare to discover i-bodies as



diagnostic imaging agents against Granzyme B, a biomarker of response to immunooncology drugs.

AdAlta's strategy is to maximise the products developed using its next generation i-body platform by internally discovering and developing selected i-body enabled product candidates against GPCRs implicated in fibrosis, inflammation and cancer and partnering with other biopharmaceutical companies to develop product candidates against other classes of receptor, in other indications, and in other product formats.

Further information can be found at: https://adalta.com.au

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i-bodies: next generation protein therapeutics for difficult targets

Investor Presentation Oct 2020



AdAlta Limited (ASX:1AD)

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Disclaimer

Investment in AdAlta is subject to investment risk, including possible loss of income and capital invested. AdAlta does not guarantee any particular rate of return or performance, nor do they guarantee the repayment of capital.

This presentation is not an offer or invitation for subscription or purchase of or a recommendation of securities. It does not take into account the investment objectives, financial situation and particular needs of the investor. Before making any investment in AdAlta, the investor or prospective investor should consider whether such an investment is appropriate to their particular investment needs, objectives and financial circumstances and consult an investment advisor if necessary.

This presentation may contain forward-looking statements regarding the potential of the Company's projects and interests and the development and therapeutic potential of the company's research and development. Any statement describing a goal, expectation, intention or belief of the company is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercialising drugs that are safe and effective for use as human therapeutics and the financing of such activities. There is no guarantee that the Company's research and development projects and interests (where applicable) will receive regulatory approvals or prove to be commercially successful in the future. Actual results of further research could differ from those projected or detailed in this presentation. As a result, you are cautioned not to rely on forward-looking statements. Consideration should be given to these and other risks concerning research and development programs referred to in this presentation.



AdAlta: clinical stage discovery company, platform poised for growth

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Grow by building multiple i-body-enabled assets

Build pipeline of assets with validated technology:

- ✓ Continue to add value to AD-214 and GE Healthcare assets
- ✓ Add internal pipeline assets in AdAlta sweet spot
- ✓ Add external pipeline assets: partner target, funding plus i-body

3

Lead external asset: GE Healthcare target - commercial validation

i-body enabled PET imaging agent to identify responders in \$100 billion immuno-oncology market

2

Lead internal asset: AD-214 anti-fibrotic product in Phase I - clinically validates platform

First-in-class, clinical stage for \$3 billion Idiopathic Pulmonary Fibrosis (IPF) market and other fibrotic diseases

1

Patented i-body platform: unique asset creation capability

Unique single domain antibody-like platform design for drug discovery against targets that challenge traditional antibodies



2020 achievements





Grow by creating and advancing i-body-enabled assets

- Growth strategy and internal discovery "sweet spot" defined
- \$8.1 million raised in fully subscribed placement and rights issue to accelerate growth trajectory



Lead external asset: GE Healthcare target - commercial validation

- Completed three discovery stages; final lead optimization stage completes Q1'21
- \$1.15 million milestones and research fees earned to 30 Sept



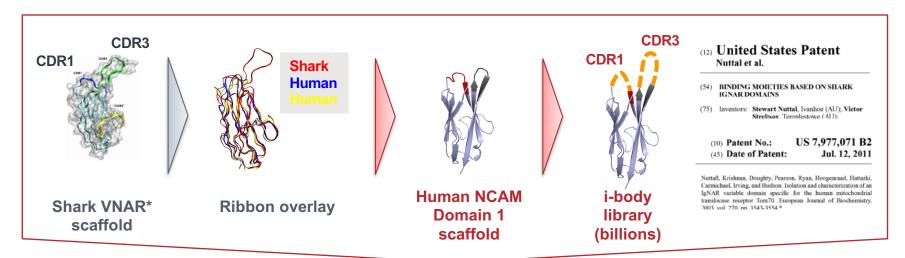
Lead internal asset: AD-214 anti-fibrotic product in Phase I - clinically validates platform

- Pre-clinical efficacy, safety complete; BTB grant for PET tracer; US FDA pre-IND meeting
- Phase I clinical trial commenced; 4 of 7 dose levels in healthy subjects complete; safety data Q1'21

Patented i-body platform: unique, validated capabilities against difficult targets



i-bodies: designed for "difficult to drug" targets





First fully human single domain antibody scaffold



Advantaged over traditional antibodies: unique target access and binding, many possible formats



First shark motif scaffold in clinical trials



>25 targets "hit": GPCRs, ion channels, enzymes, ligands, protein interfaces



Lead asset AD-214: first-in-class anti-fibrotic

CXCR4 receptor is critical player in development of fibrosis in many organs

Normal Inug tissne



Brown stain shows amount of CXCR4

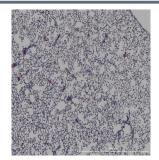
AD-214 specifically designed for fibrosis

- Novel pharmacology
- Granted patents expire 2036

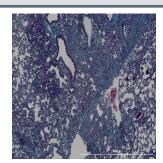
AD-214 is first in class: the only CXCR4 antagonist being developed for fibrosis

Potential in multiple fibrotic and cancer indications

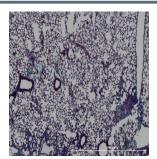
Efficacy demonstrated in gold standard Idiopathic Pulmonary Fibrosis (IPF) mouse model



Normal mouse lung tissue



IPF mouse lung tissue (21 days after bleomycin [BLM])



IPF mouse lung tissue + AD-214 (21 days after BLM; AD-214 at 10mg/kg every 4 days from day 8)



Lead indication IPF: \$3b market, poor options

Idiopathic Pulmonary Fibrosis (IPF) is irreversible, unpredictable, incurable

>300,000

people living with IPF

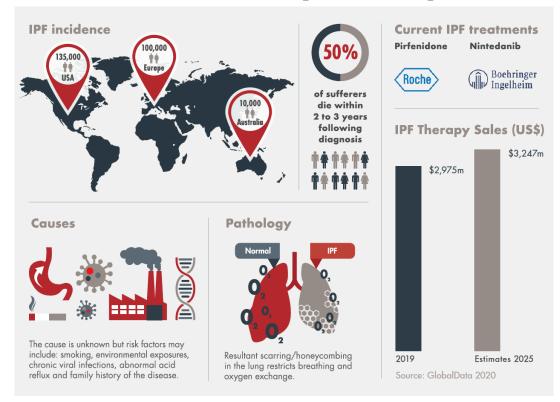
40,000

people die from IPF every year

3.8 years

median survival after diagnosis

Current treatments come with safety, efficacy limitations



Burden of fibrotic lung disease following COVID-19 likely to be high

"Antifibrotic therapies could have value preventing severe COVID-19 in IPF patients and preventing fibrosis after SARS-CoV-2 infection"



Current phase I clinical trial

September '20 status

- 20 subjects, 4 of 7 dose levels
- Into potential therapeutic window
- No dose limiting adverse events observed to date

Part A 4

(Results early 2021)

Part B

(early 2021 to late 2021)

Part C

(late 2021 to mid-2022)

Multiple dose.

ILD/IPF patients

(Pax MAD)



Pre-IND meeting

- Pre-clinical studies "generally sufficient" to support an IND application
- Phase I trial design is "reasonable"

Single dose, healthy volunteers (HV SAD)

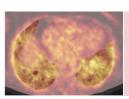
~44 subjects



Single dose, ILD/IPF patients (Pax SAD)

• ~15-30 subjects

• ~12-24 subjects



Developing AD-214 PET tracer to show distribution and receptor occupancy

A\$1m BTB grant funding





















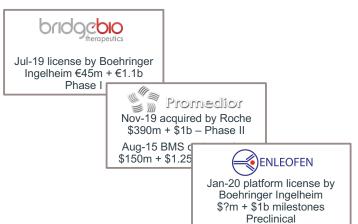
Multiple options in play for AD-214

Phase I data

- Safety
- PK
- Receptor occupancy
- Receptor distribution

Early partnering options

- Active early stage partnering landscape
- Novel mode of action expected to be attractive
- First partnering window end of Phase I



Indication extension options

- IPF/ILD and other fibrotic indications
- Metastatic cancer, I/O combinations
- Animal data in >5 additional indications
- Markets worth US\$2-15 billion each



Skin

SCLERODERMA

CARDIAC FIBROSIS

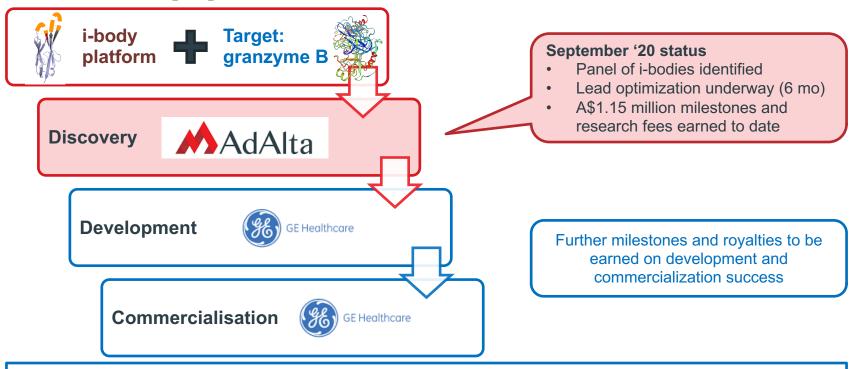
Kidney

RENAL FIBROSIS

Blocking CXCR4 alleviates desmoplasia, increases T-lymphocyte infiltration, and improves immunotherapy in metastatic breast cancer Ivv X. Chen^{a,b,c}, Vikash P. Chauhan^{a,b}, Jessica Posada^{a,d}, Mei R. Ng^a, Michelle W. Wu^a, Pichet Ac



External pipeline: multi-national GE Healthcare

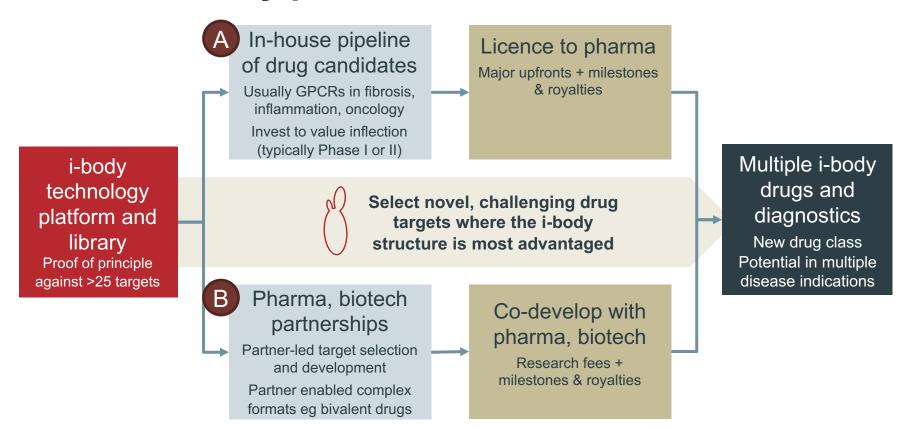


Opportunity: PET imaging GZMB

- US\$100 billion immuno-oncology market by 2025
- ~30% patients respond; granzyme B (GZMB) a biomarker for responders
- PET imaging GZMB could significantly improve therapy selection, outcomes

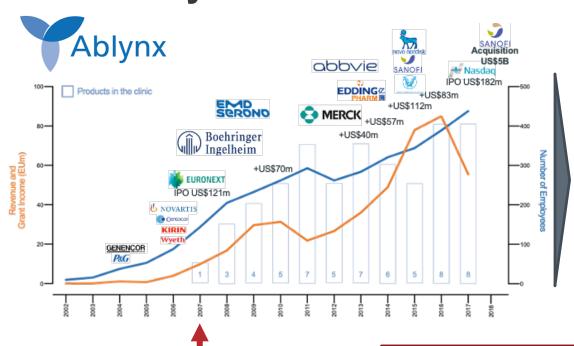


AdAlta's twin strategies to create valuable assets from the i-body platform





Single domain antibody platform potential: Ablynx case study



Ablynx strategy (2007)

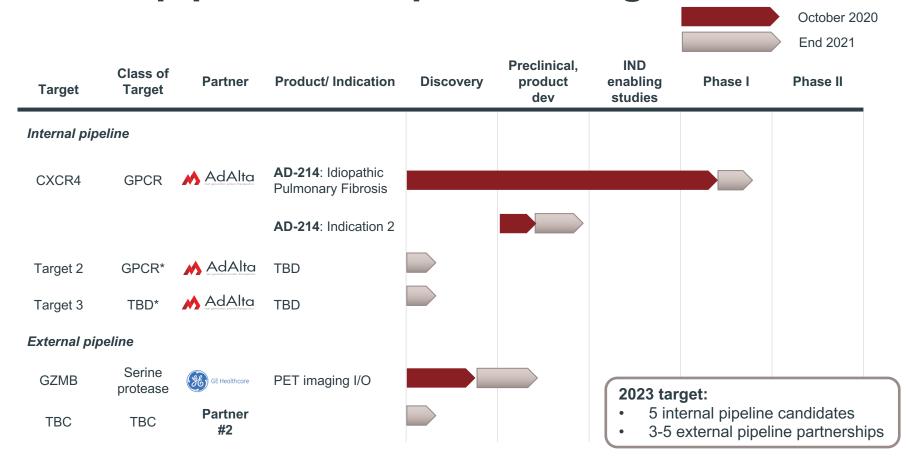
- A. Leverage platform to rapidly identify potential drug candidates
- B. Drive lead product candidate through clinical development
- C. Selectively partner to maximize market opportunity
- D. Maintain and expand technology and IP position

Comparator position: year first product reaches clinic
Opportunity: use first clinical trial as catalyst for acceleration





AdAlta pipeline to expand through 2021





Key execution milestones

Strategic priority	2020 YTD achievements	H2 2020	H1 2021	H2 2021
AD-214 clinical progression	US patent Pre-clinical efficacy, PK/PD Phase I approval FDA pre-IND advice Phase I Part A: first participant	Phase I Part A (HV) interim drug safety committee findings* PET tracer pre-clinical proof of concept (PET images in mouse)*	Phase I Part A (HV): top line safety, PK/PD results* Phase I Part B (ILD) first patient, first PET images Expanded clinical plans: proof of concept data, program definition	Phase I Part C (ILD) first patient multi-dose First partnering window opens Manufacturing process optimised, scaled for late stage clinical trials IND preparation begins
Internal pipeline assets External pipeline assets	GE Healthcare stage 2 milestone	 GE Healthcare stage 3 milestone*	 First new targets selected Second platform partnership	 2-3 new i-bodies progressing
i-body platform asset	AdAlta strategy update			i-body 2.0 scaffold developed, IP filed

Industry experienced leadership and advisors

Board



Dr Paul MacLeman Chair







Tim Oldham, PhD CEO & Managing Director







Liddy McCall (alt: Dr James Williams) Director b Dimerix 🏻 🍇 iCeutica



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Kevin Lynch, MD Consultant Medical Expert



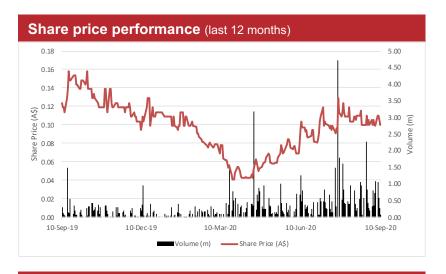




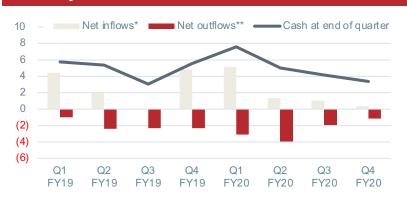
Financial position

Key financial details (11 Sep)	
ASX code	1AD
Market capitalisation	A\$24.52m
Share price (12 month range)	A\$0.10 (\$0.04-0.16)
Ordinary Shares (daily volume)	245,175,853 (309,506)
Listed Options	23,348,803
Unlisted Options	7,514,067
Cash (30 June 2020)	A\$3.37m
Placement, Rights Issue (Sep'20)	A\$8.1m

Major shareholders (11 Sep)	%
Yuuwa Capital LP	22.0
Platinum Asset Management	11.6
Meurs Holdings Pty Ltd	7.3
CS Third Nominees Pty Ltd	3.1
Citicorp Nominees Pty Ltd	2.0
Other	54.0
Total	100%



Quarterly cash flows





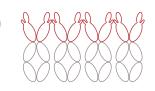
AdAlta (ASX:1AD) Investment proposition

- Patented i-body platform for asset creation: designed for "difficult" targets
 - Unique structure, properties addresses targets that challenge traditional antibodies
- ▶ AD-214: clinical stage first-in-class asset for fibrosis
 - Phase I trial underway in US\$3 billion orphan disease idiopathic pulmonary fibrosis (IPF)
 - Part A top line safety data + Part B PET images H1 2021
 - Partnering window opening towards end of 2021
 - Pre-clinical data available, emerging in multiple fibrotic indications and cancer
- GE Healthcare: commercial validation of platform
 - Partner funded discovery program; progressed to lead optimisation
- ▶ Clear vision for growing existing assets and adding more; A\$8m funding in place
 - AD-214: Phase I patient data, expand indications, partner
 - Internal pipeline: GPCRs in fibrotic, inflammatory disease and cancer (2-3 new assets by end 2021)
 - External pipeline: partner selected and funded targets: 2nd partnership by mid-2021
 - Platform leadership: continuous improvements to i-body platform, formulation and manufacturing
- Experienced drug development team driving strategic focus
- ▶ Unique investment opportunity: validated platform, cash runway, ready to realize expansion potential













Contacts for more information:

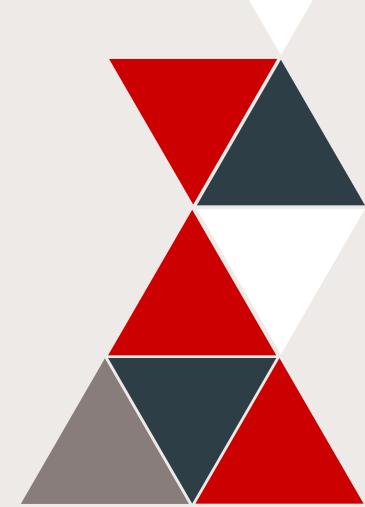
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APPENDIX: DETAIL

Growth trajectory to build value

A Maximise catalysts from current funded base (2020)

Market Cap: A\$25 million
(11 Sep 2020)

Accelerate (from ~mid-2021)

Expand
(~mid 2020 to late 2021)

ASX:1AD

From ...

- i-body platform in clinic for difficult drug targets
- Clinical and commercial validation: AD-214 Phase I trial and GE partnership

Via ...

- · Laying the foundations for growth
- Progress AD-214
 Puild internal and
- Build internal and external pipeline
 Continuous platform improvement
- Continuous platform improvement

Towards 2023 ...

- Multi-product, multi-partner platform company
- AD-214 partnering, new indications
- ~5 internal GPCR programs
- 3-5 co-development partnerships



Near term strategic priorities (expansion phase)

Create value inflections for lead asset AD-214

- Clinical development in IPF/ILD
- Expand indications, create licensing options

Add 2 assets to *internal* pipeline in our "sweet spot"

- G-protein coupled receptors (GPCRs)
- Fibrosis, inflammation, cancer

Add to *external* pipeline through a new partnership

• Earlier revenue; access to additional target expertise

Continuous i-body platform and AD-214 product improvement

• Ensures continued technology leadership, competitive advantage



Market benchmarks: reaching for the stars!

Fibrosis pipelines



Jul-19 license by Boehringer Ingelheim €45m + €1.1b Phase I



Promedior

Nov-19 acquired by Roche \$390m + \$1b - Phase II

Aug-15 BMS option to buy \$150m + \$1.25b milestones



Jan-20 platform license by Boehringer Ingelheim \$?m + \$1b milestones Preclinical

Microantibody platforms



April-16 license by Abbvie \$40m upfront + \$645m milestones & royalties



Feb-18 collaboration with Seattle Genetics (3 targets)

> \$30m upfront + \$1.2b milestones & royalties



Feb-18 acquired by Sanofi €3.9b

GPCR platforms



Feb-15 acquired by Sosei \$400m Phase Ib asset + 7 preclinical leads



v receptos

Jul-15 acquired by Celgene \$7.8b Ph III, Ph II and GPCR platform

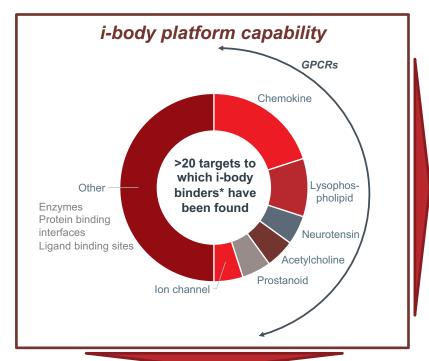


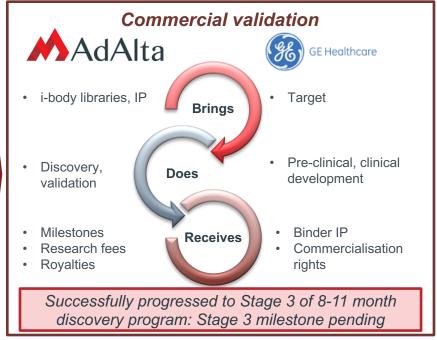
April-16 license with Boehringer €8m + €125m milestones

Phase I GPCR nanobody



Pipeline: diverse target capability supports internal and external pipeline assets





Internal pipeline asset creation

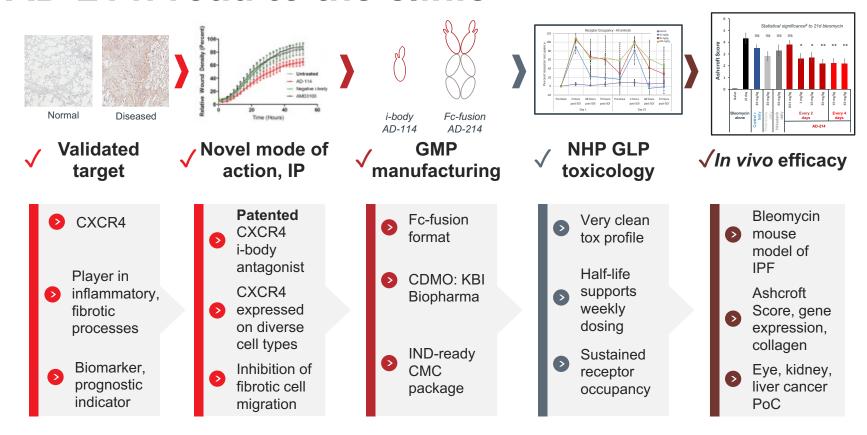
- G-protein coupled receptors
- Fibrosis, inflammation, oncology

External pipeline asset creation

- Multiple co-development partnerships
- New target biology, non-dilutive funding



AD-214: road to the clinic





NHP GLP toxicology: AD-214 safe

3 non-human primate studies completed

Good Laboratory Practice (GLP) study to evaluate safety and toxicology

- ▶ 10mg/kg, 30mg/kg and 100mg/kg multiple doses over four weeks plus recovery (human equivalent dose 32mg/kg)
- AD-214 well tolerated with no deaths, no AD-214-related clinical signs, no changes in a panel of clinical observations
 - body weight

- electrocardiography
- coagulation

 macroscopic and microscopic findings

- ophthalmoscopy
- respiratory function
- urinalysis

- blood pressure
- neurological function

- organ weight
- 3 3
- ▶ Minor, transient, completely reversible increase in total white cell and circulating CD34+ cells
- Small, transient, completely reversible decrease in serum total protein and albumin at highet dose only (100 mg/kg)

Tox study results were in line with expectations and in keeping with previous studies

No major organ toxicity has been observed on repeat dosing at high doses

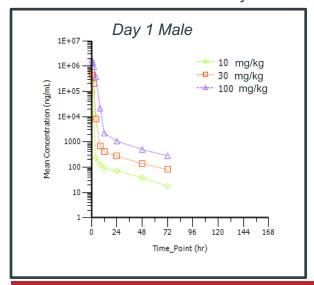
No suggestion of off-target toxicities



Non-human primate GLP toxicology: Phase I dose justification

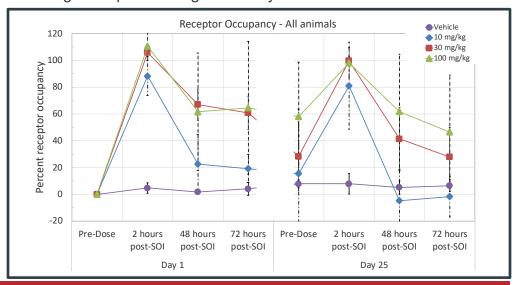
Pharmacokinetics

- Elimination half-life 22-29h
- Human equivalent: ~71h (estimate)
- AD-214 available for >3 days



Pharmacodynamics

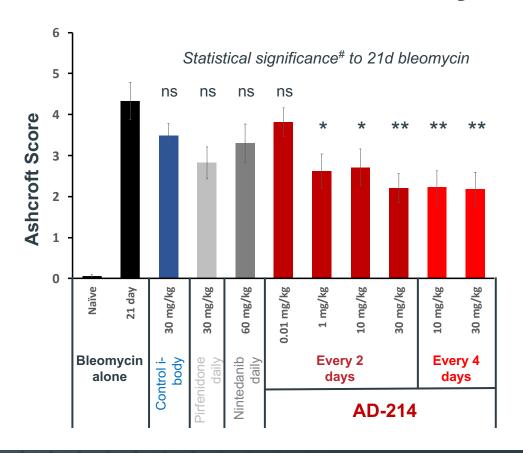
- >60% receptor occupancy* for 72h at >30mg/kg
- Human equivalent: ~10mg/kg (estimate)
- High receptor binding for >3 days



Supportive of human therapeutic dose window including 10mg/kg intravenously, weekly or every second week



AD-214 induced reduction in progression of fibrosis in mouse bleomycin model



- AD-214 reduced Ashcroft Score with statistical significance compared to bleomycin treated mice at:
 - 1-30mg/kg every second day
 - 10-30mg/kg every fourth day
- Wide range of dosing regimens can be used to test efficacy
 - 10mg/kg every second day exhibited effectiveness by most study parameters
 - Human equivalent dose: 1mg/kg (estimated)

AD-214 efficacy demonstrated in gold standard IPF disease model

Supportive of potential human therapeutic window beginning as low as 1mg/kg



Phase I design detail*

Phase I, dose-escalating study of the safety, tolerability, PK & PD of single and repeat doses of AD-214 in healthy volunteers (HVs) and patients with interstitial lung disease (ILD)

Part A

(Ongoing to early 2021)

Part B

(early 2021 to late 2021)

Single dose,

ILD/IPF patients

(Pax SAD)

Part C

(late 2021 to mid-2022)

Multiple dose,

ILD/IPF patients

(Pax MAD)

Objectives

Single dose,

volunteers (HV SAD)

healthy

- ~44 subjects
- 0.01-20 mg/kg iv
- 1 site



~15-30 subjects**

- 0.1-20 mg/kg iv
- 2-3 sites

- ~12-24 subjects**
- iv weekly, 4 weeks
- 2-3 sites

Primary

Safety, tolerability of AD-214

Secondary

- PK, PD of AD-214
- Immunogenicity of AD-214

Exploratory

- Effect of AD-214 on respiratory function
- Localisation/distribution of 89Zr-AD-214 by PET-CT***



Includes AD-214 PET tracer for distribution and receptor occupancy

Contracted vendors

Partners in development and clinical validation of PET tracer for Parts B and C

























