10 March 2021

ASX Announcement

AD-214 Phase I study: positive data expands opportunities for AdAlta

MELBOURNE Australia, 10 March 2021: AdAlta Limited (ASX:1AD), a clinical stage biopharmaceutical discovery and development company using i-body technology to address challenging drug targets is hosting an investor briefing at 1100 AEDT today to discuss top line results from Part A of its Phase I clinical program studying single ascending doses (SAD) of lead asset AD-214 in healthy volunteers (HVs).

Highlights of the briefing include:

- Part A of the AD-214 Phase I program (HV SAD) has been successfully completed
- AD-214 is very well tolerated in single doses up to 20 mg/kg in healthy volunteers
- AD-214 engages its target receptor, CXCR4, and sustains higher levels of receptor occupancy for longer than predicted
- These results enable a more efficient program for the remainder of Phase I, generating more data more rapidly for the same cost
    - Part B will now be a multiple ascending dose study in HVs, enabling a safety package supportive of a Phase II US FDA Investigational New Drug (IND) application to be obtained by end of 2021
    - A longer dosing interval will be explored for clinical convenience
    - Patient studies will be conducted under a separate Phase Ib protocol incorporating a radio-labelled version of AD-214 for PET imaging. This achieves the originally planned exploration of the effect of elevated CXCR4 in Interstitial Lung Disease (ILD) and Idiopathic Pulmonary Fibrosis (IPF) patients on AD-214 safety, pharmacokinetics and receptor occupancy. In addition, this protocol may also explore distribution of AD-214 in other fibrotic indications, the effect of AD-214 when administered over 18 weeks, and the safety of AD-214 when used in combination with standard of care therapies. This data could support expansion into additional indications.
- This clinical validation of the i-body platform is anticipated to increase partner interest in both AD-214 and co-development opportunities, contributing significantly to the acceleration of AdAlta's asset creation strategy. The Company aims to have 9 products in discovery research through to Phase II by the end of 2023.

The presentation to be discussed at the briefing is attached. A limited number of online seats to the briefing are still available: register to receive a link to the briefing via lauren.byrne@irdepartment.com.au.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
February 2021

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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 immuno-oncology 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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AdAlta

next generation protein therapeutics

AD-214 Phase I study: positive data expands opportunity

Investor Briefing 10 March 2021

AdAlta Limited (ASX:1AD)

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Agenda today

- **Strategic progress**
  Tim Oldham, CEO and Managing Director
- **AD-214 Phase I HV SAD top-line results**
  Claudia Gregorio-King, VP Clinical Product Development
- **Context: importance for IPF**
  Prof Glen Westall, leading respiratory and lung fibrosis specialist
- **Next steps**
  Tim Oldham, CEO and Managing Director

Today's highlights

- ✓ Single ascending dose (SAD) healthy volunteer (HV) study **successfully completed**
- ✓ AD-214 is **very well tolerated** in single doses to 20 mg/kg in healthy volunteers
- ✓ AD-214 **engages its target receptor,** CXCR4, and sustains high levels of receptor occupancy

- ➢ Results enable **more efficient program** for remainder of Phase I including:
  - **Extended dosing interval** for patient/clinician convenience
  - **Phase I safety** dosing to complete by **end 2021**
  - Delivers **safety package supportive of** Phase II US FDA Investigational New Drug (IND) application in **any CXCR4 mediated indication**
  - **Parallel Phase Ib patient studies** to explore effect of fibrotic disease on safety, PK, distribution and receptor occupancy of AD-214

Initial clinical validation i-body platform strengthens AdAlta's asset creation options

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Agenda today

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Next steps
Tim Oldham, CEO and Managing Director

AdAlta is rapidly transforming to a multi-asset company

4 Executing growth: creating multiple i-body-enabled assets

- **$8.1 million raised Sep 2020 in placement and rights issue**
- **Progressing new internal product ideas: 2 programs to start 2021**
- **Encouraging business development pipeline**
- **One new co-development program forecast for 2021**

3 Lead external asset: GE Healthcare target in lead optimisation

GE Healthcare

- **$1.15 million milestones and research fees received to 31 Dec 2020**
- **Lead optimization stage completes Q1 2021**

2 Lead internal asset: AD-214 a first in class anti-fibrotic in Phase I clinical trial

- **US FDA pre-IND meeting, Orphan Drug Designation**
- **Phase I: excellent safety profile, sustained high receptor occupancy (single dose, healthy subject)**

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

- **First fully human single domain antibody platform; first based on shark motif to reach the clinic**
- **Now clinically and commercially validated**
- **Next generation improvements in development to maintain technology leadership**

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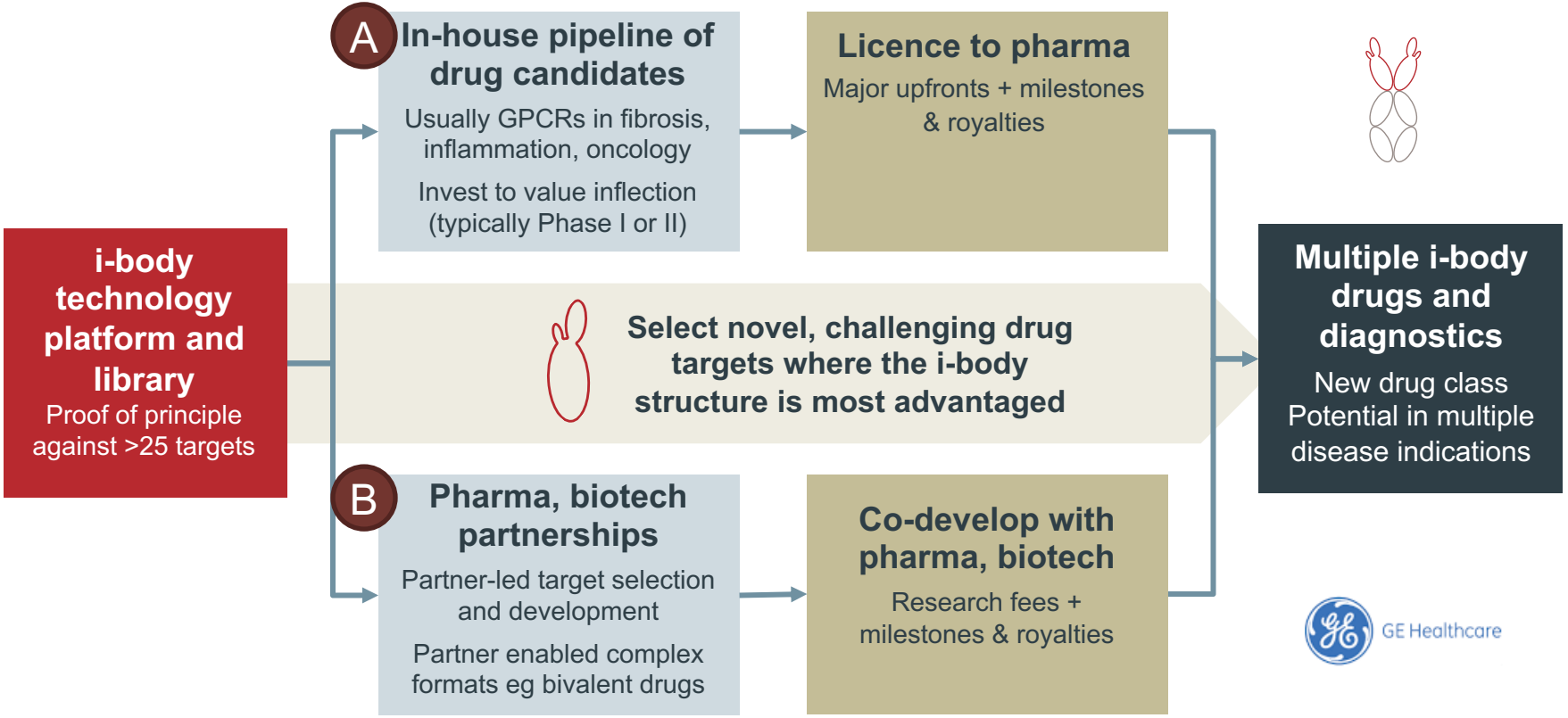
AdAlta has two strategies to create valuable assets from the i-body platform



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Near term strategic priorities set March 2020

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

Strategic priorities: progress to March 2021

	March 2021 status
Create value inflections for lead asset AD-214	• Phase I clinical program started: **top-line single dose results today** • Pre-IND meeting and Orphan Drug Designation secured from FDA • Pre-clinical data in kidney fibrosis; studies in eye, cancer underway • On track to confirm next two indications for AD-214 • Partnering pipeline developing well
Add 2 assets to ***internal*** pipeline in our "sweet spot"	• Developed selection process • Screened existing targets, now extending to other GPCRs* • On track to commence discovery research on two targets in H2 2021
Add to ***external*** pipeline through a new partnership	• GEHC progressed to lead optimisation • Co-development partnering pipeline developing well • On track to execute second collaboration by mid 2021
Continuous i-body platform and AD-214 product improvement	• Encouraging progress made on i-body2.0, manufacturing and high throughput discovery methods

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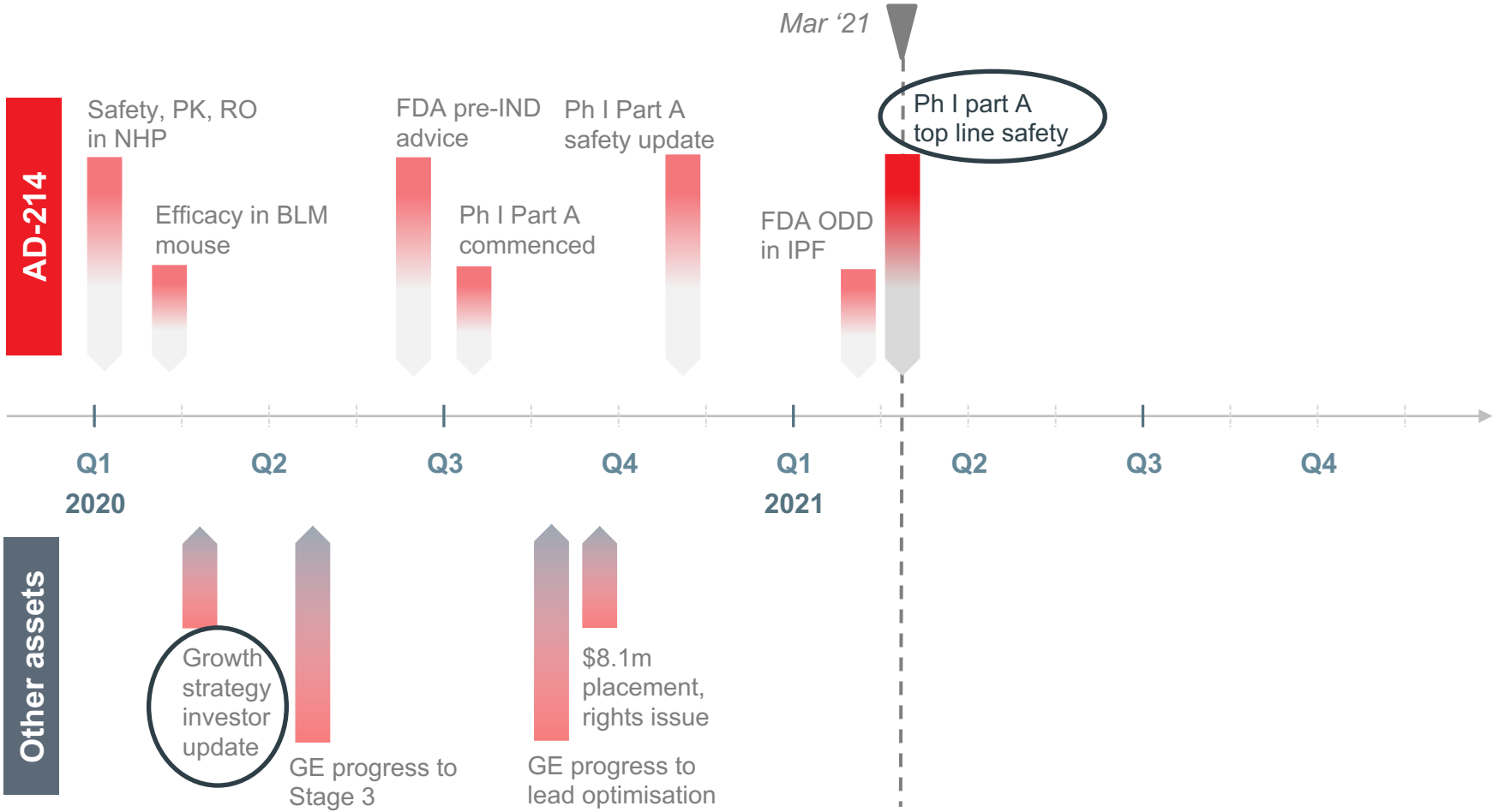
Major milestones achieved since March 2020



FDA engagement: AD-214

Pre-IND meeting June 2020

- Pre-clinical studies “generally sufficient” to support an IND application
- Phase I trial design is “reasonable”
- Minor feedback readily incorporated into clinical trial design and ongoing pre-clinical and CMC studies

Orphan Drug Designation granted for AD-214 in IPF February 2021

Office of Orphan Products Development
Food and Drug Administration
WO32- 5295
10903 New Hampshire Avenue
Silver Spring, MD 20993

Intrinsik Health Sciences (US), Inc.
Suite 202, 41 Campus Drive
New Gloucester, Maine 04260

Attention: Dwayne R.J. Moore, PhD
Senior Vice President
dmoore@intrinsik.com

Re: Designation request # DRU-2020-8004
Dated: 11/27/2020
Received: 11/30/2020

Dear Dr. Moore:

This letter responds to your request submitted on behalf of AdAlta Limited for orphan-drug designation of Fc-fusion protein comprised of an anti-CXCR4 i-body (AD-114) tethered at its C-terminus to constant domains 2 and 3 of the Fc region of a mutated human IgG1 for “treatment of idiopathic pulmonary fibrosis.”

Pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), your orphan-drug designation request of Fc-fusion protein comprised of an anti-CXCR4 i-body (AD-114) tethered at its C-terminus to constant domains 2 and 3 of the Fc region of a mutated human IgG1 is granted for *treatment of idiopathic pulmonary fibrosis*. Please be advised that it is the active moiety or principal molecular structural features of the drug[1] and not the formulation of the drug that is designated.

Agenda today

Strategic progress

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Context: importance for IPF

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Next steps

Tim Oldham, CEO and Managing Director

Preliminary healthy volunteer single dose results

AD-214 has an excellent safety profile

Database lock and full statistical analysis pending

- No dose limiting toxicities or adverse events of clinical concern
- No concerning clinical laboratory results
- Consistent with Non-Human Primate (NHP) toxicology studies

AD-214 engages the CXCR4 receptor

- Clear markers of target (CXCR4) engagement observed

Receptor occupancy sustained at high levels for extended periods

- Supportive of longer dosing interval than projected from NHP if replicated in patients

Enables redesign of remainder of Phase I program to:

- Explore more clinically convenient dosing interval
- Deliver Phase II IND ready safety for multiple indications
- Explore multiple doses in patients over longer period

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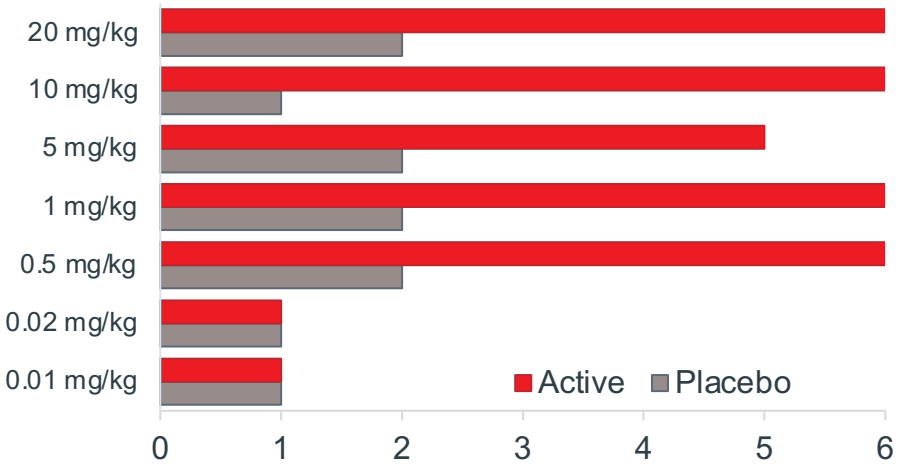
AD-214 Phase I Part A design detail*

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

Part A: Single ascending dose in healthy volunteers

Patient numbers by cohort

Total n=42 (31 active, 11 placebo, blinded)



CMAX CLINICAL RESEARCH scientia CLINICAL RESEARCH 360biolabs ENABLING FUTURE MEDICINES CNS Intelligent Development

Objectives

Primary

- Safety, tolerability of AD-214
  - adverse events, physical examinations, vital signs, ECG
  - clinical laboratory tests (hematology, chemistry, coagulation, cytokines)

Secondary

- PK, RO of AD-214
- Immunogenicity of AD-214

Exploratory

- PD markers (SDF-1, CD34+)

* https://clinicaltrials.gov/ct2/show/NCT04415671?term=adalta&draw=2&rank=1

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Single dose of AD-214 is well tolerated

Adverse events (unblinded data)

- No dose limiting adverse events
- No serious adverse events
- No concerning clinical laboratory results
- Dose escalation steps completed without concern
- **Adverse events were non-concerning**
  - Predominantly mild
  - Three Grade 2 (moderate) adverse events

Immune response*

- Isolated incidences of minor cytokine elevation
  - Transient and primarily low level elevation of IL-6 and IL-8 in some participants (including placebos)
- No clinically significant cytokine release
- Antidrug antibodies: detected in 11 participant
  - Predominantly low titre
  - Characterisation pending
- **No clinical symptoms related to immune response observed**

* Based on unblinded data, active drug participants assumed to be those for whom pharmacokinetic C_{max} was determined

AD-214 pharmacokinetics increase proportionally with dose

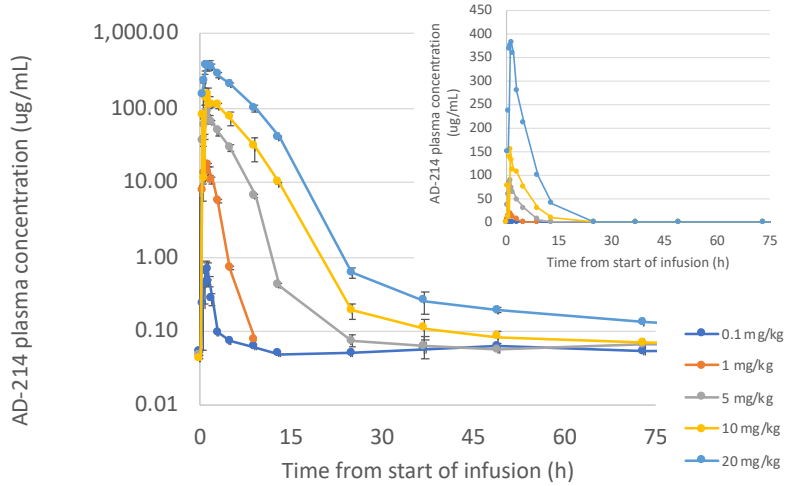
Observed in NHP GLP toxicology study

- Maximum exposure, C_{max}, increases in a dose proportional manner
- Total exposure, $AUC_{0\text{-}inf}$, increases in a more than dose proportional manner
- Elimination half-life $t_{1/2}$ 22-29 h

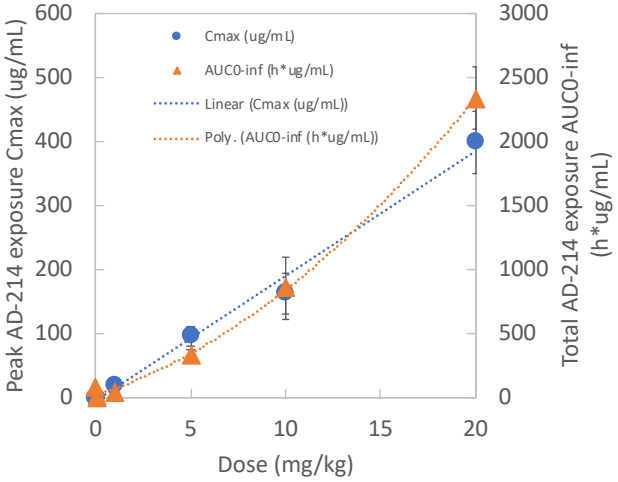
Observed in Phase I HV SAD

- Maximum exposure, C_{max}, increases in a dose proportional manner
- Total exposure, $AUC_{0\text{-}inf}$, increases in a more than dose proportional manner
- Elimination half-life $t_{1/2}$ = 44±15 h

AD-214 plasma concentrations (log and linear scale)



Maximum and total plasma exposure



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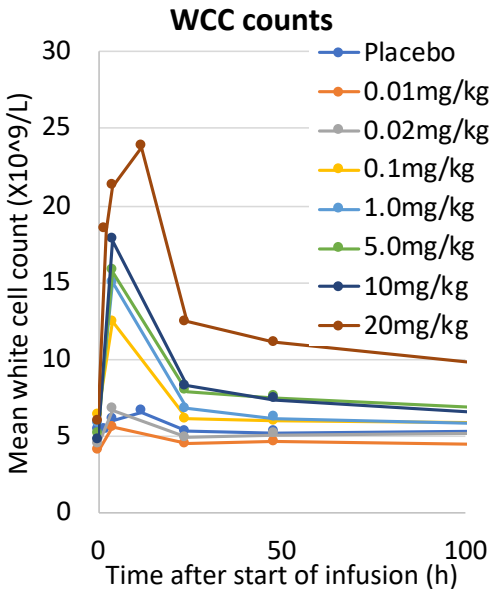
Transient white blood cell and blood stem cell increases indicate CXCR4 engagement

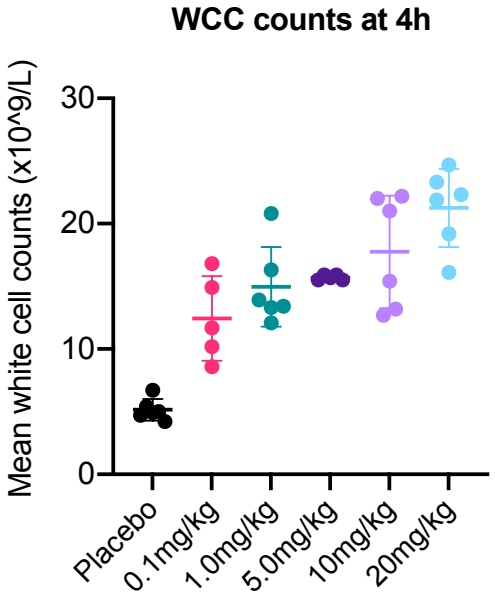
Observed in NHP GLP toxicology

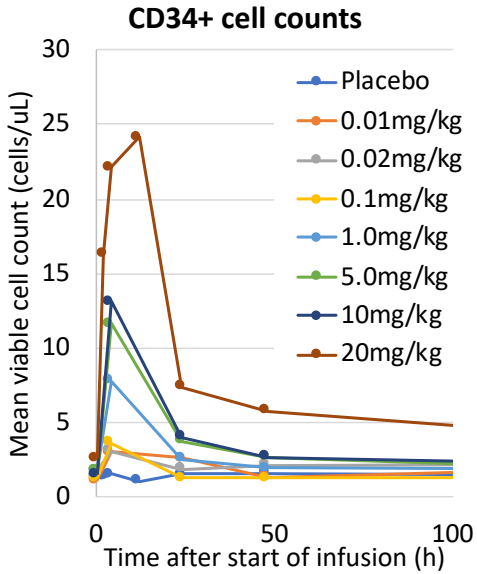
- Transient increase in white cell counts (WCC) and blood stem cell (CD34+) cell counts

Observed in Phase I HV SAD*

- Transient, dose dependent, increase in WCC and CD34+ counts at 4-12 hours consistent with CXCR4 blockade







* Based on unblinded data, CD34+ incudes only participants for whom pharmacokinetics C_{max} was determined

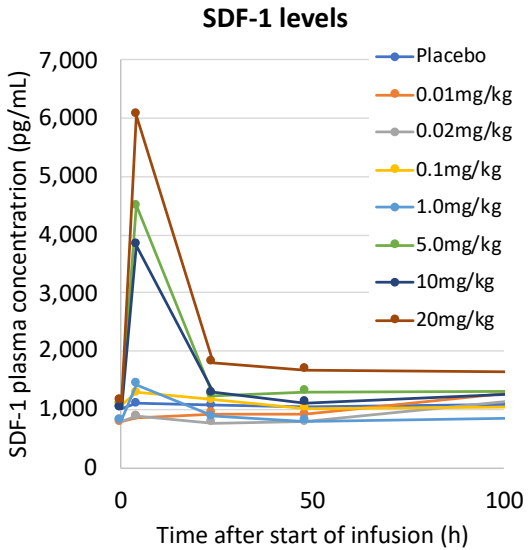
Transient increase in SDF-1 (natural ligand of CXCR4) suggests CXCR4 engagement

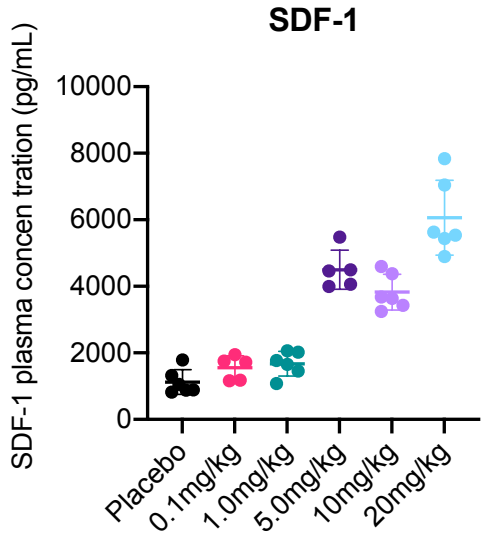
Expected from literature and prior studies

- Transient increases in SDF-1 levels in response to CXCR4 blockade, high participant to participant variability

Observed in Phase I HV SAD*

- Transient increases in SDF-1 levels at 4 hours in some participants, returning to baseline at 24h consistent with CXCR4 blockade





* Based on unblinded data, includes only participants for whom pharmacokinetic C_{max} was determined

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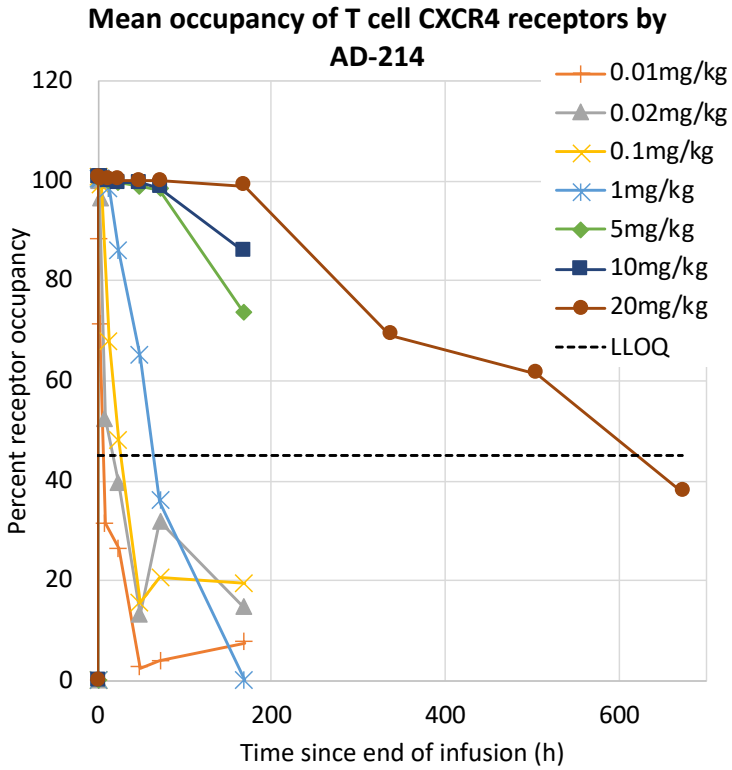
Sustained high levels of CXCR4 receptor occupancy on T cells



White blood cells naturally express CXCR4 in healthy individuals, providing an accessible surrogate for AD-214 target engagement or receptor occupancy (RO)

Understanding duration of RO is critical to inform dosing

Observed in NHP GLP toxicology

- >50% CXCR4 receptor occupancy (RO) on T cells at four days after infusion of 10-20 mg/kg

Observed*

- Dose dependent level and duration of RO
- >70% CXCR4 RO at 7 days after 5-10 mg/kg infusion
- >60% CXCR4 RO at 21 days after 20 mg/kg infusion**
- ***Duration of RO is considerably longer than PK profile***

If replicated on CXCR4 receptors in fibrotic tissues, result supports extended dosing intervals despite relatively rapid clearance from circulation

* Based on unblinded data, incudes participants for whom PK C_{max} was determined, placebo excluded
** Receptor occupancy was monitored for one week at all dose levels except 20 mg/kg (4 weeks)

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More efficient design for remainder of Phase I

Current approved Phase 1 protocol

Part A: HV SAD
Blinded/placebo controlled
7 cohorts
Up to 44 pts
✓

Part B: IPF/ILD SAD
Unblinded/no placebo
5 cohorts
15 – 30 pts

Part C: IPF/ILD MAD
Unblinded/no placebo
4 cohorts / once weekly dosing
12 – 24 pts

Planned more efficient next steps

Protocol amendment submitted*
- Treatment complete end 2021
- Safety data supports Phase II in all AD-214 indications (iv route)

Part B: HV MAD
Blinded/ Placebo controlled
5-15 mg/kg every 2 weeks
3 cohorts, 12 – 24 pts

New exploratory Phase Ib protocol in preparation*
- Anticipated commence Q3 2021
- Demonstrates AD-214 distribution and CXCR4 receptor occupancy in tissue in a range of indications
- Determines impact of disease on AD-214 PK parameters

Arm 1: PET screening of fibrotic diseases
Open label with SoC**
1-2 PET-CT sequences
~12 patients (~6 IPF/ILD) CXCR4 disease

Arm 2: Multi-dose in IPF/ILD
Open label with SoC**
Max 6 doses, 5-10mg/kg over 18 weeks
~6 patients +/- PET imaging

* Supported by Safety Management Committee, subject to HREC approval
** Standard of Care (includes pirfenidone, nintadanib or non-pharmacologic intervention)

Agenda today

AdAlta

Lead indication IPF: $3b market, poor options

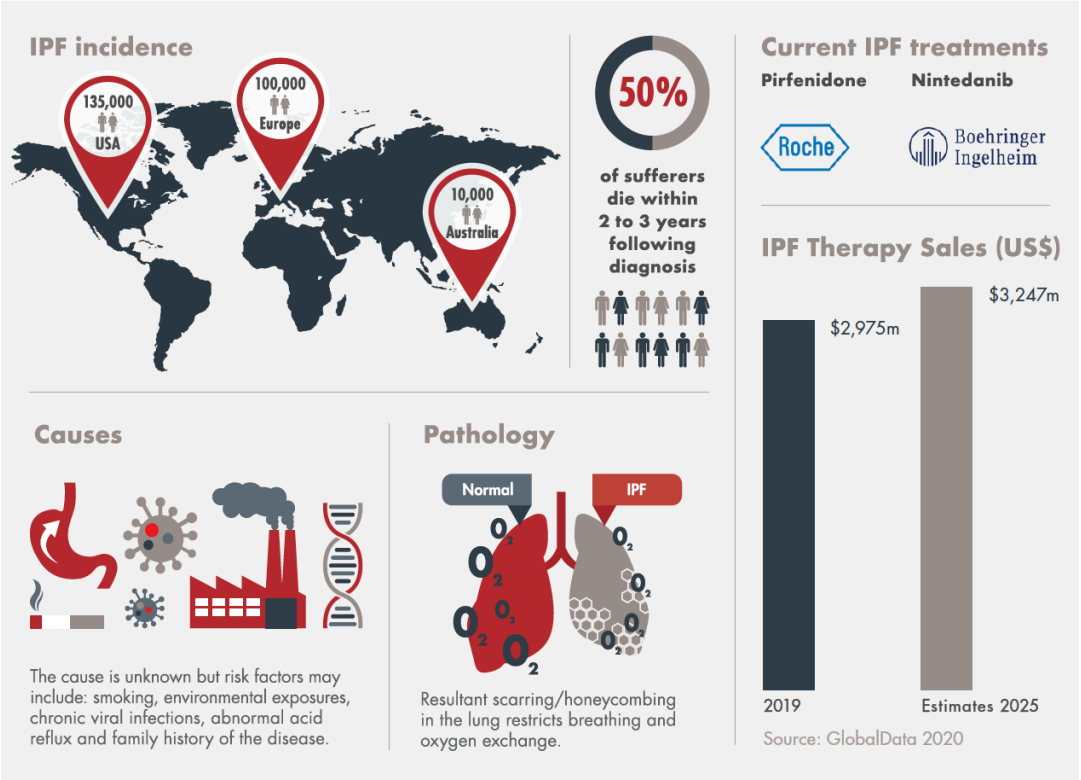
Idiopathic Pulmonary Fibrosis (IPF) is irreversible, unpredictable, incurable

>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"**

* PM George, *et al*, "Pulmonary fibrosis and COVID-19: the potential role for antifibrotic therapy", Lancet published online May 15, 2020

Limited (and decreasing) new options for patients

	Phase II	Phase III	FDA Fast Track	FDA Orphan Drug
Galápagos GLPG1690	12 weeks, 23 subjects	ISABELA 1&2: **TERMINATED** 52 weeks, 1500 subjects		✓
FibroGen Pamrevlumab	48 weeks, 103 subjects	ZEPHYRUS - ACTIVE 52 weeks, 565 subjects	✓	✓
Liminal BioSciences PBI-4050	12 weeks, 40 subjects	NO PROGRESS SINCE 2018	✓	✓
Promedior PRM-151	24 weeks, 116 subjects	Phase III initiated in 658 subjects - acquired by Roche	✓	✓
Kadmon KD025	24 weeks, 76 subjects	**NOT PROGRESSING** Focusing on other indications		✓

New therapies and combination therapies addressing multiple modes of action are required

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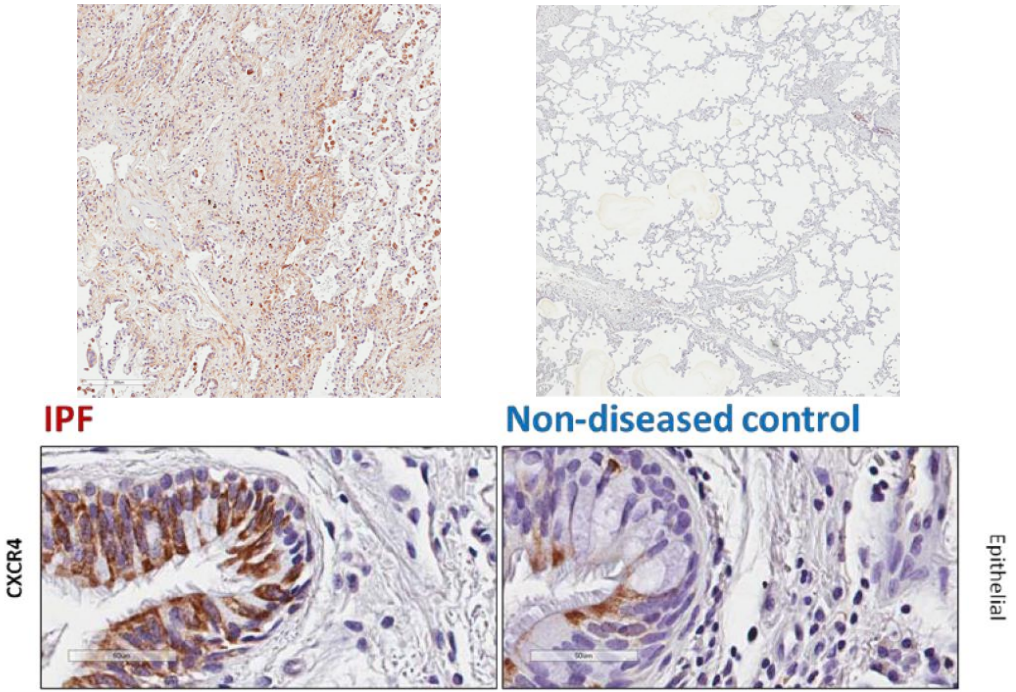
CXCR4 plays a role in IPF

CXCR4 is upregulated in IPF lung tissue

Very limited expression in normal or non-diseased tissues



Brown stain shows amount of CXCR4

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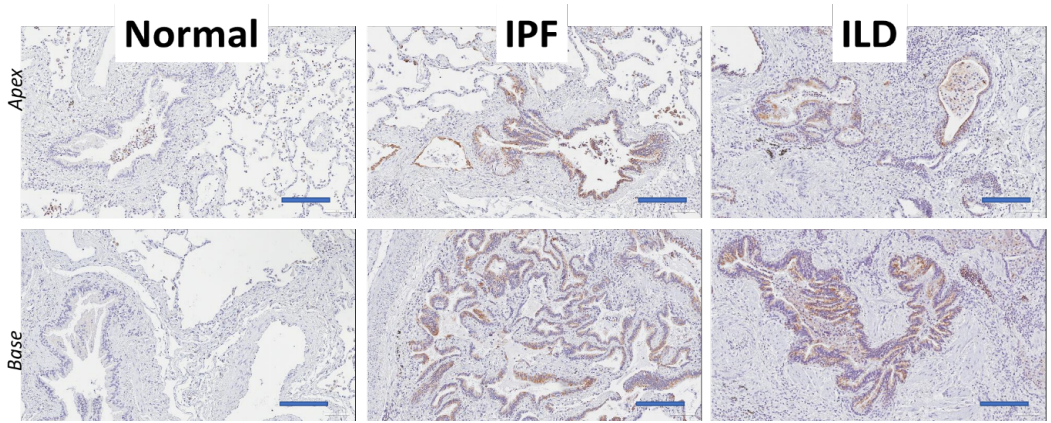
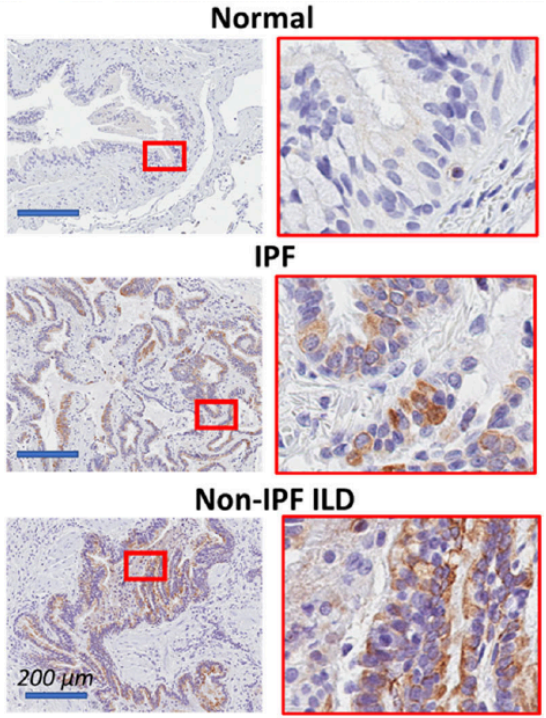
CXCR4 is expressed in both IPF and ILD patient lung tissue and in multiple cell types



- CXCR4 was abundantly expressed in **both IPF and ILF donors** compared with non-diseased controls
- CXCR4 is expressed on **circulating immune cells** and we have demonstrated that in patients with IPF and other fibrotic ILDs, CXCR4 is significantly upregulated in **fibrotic airway epithelial cells** and **myeloid cells in fibrotic loci**



CXCR4 stained brown

Source: Jaffar et al, Respiratory Research (2020) 21: 221

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Why targeting CXCR4 could improve IPF/ILD outcomes

Observation

- CXCR4 is up-regulated in ILD patients as well as IPF patients
- CXCR4 is upregulated in epithelial and myeloid cells in fibrotic tissue
- CXCR4 also mediates migration of fibroblasts and inflammatory cells such as macrophages in a disease specific way

Significance

- If AD-214 works in IPF it is more likely to work in ILD as well … and there are at least as many non-IPF ILD patients as IPF patients
- Epithelial cells trigger the fibrosis cascade: blocking CXCR4 could have a broader effect than simply shutting down collagen deposition
- Blocking CXCR4 may also have an immune modulation effect and inhibit immune/ inflammatory cell infiltration to the lungs

Implications for AD-214: a clinician's perspective

- **Un-met need in IPF/ILD** remains: need to progress new therapies
- Research at The Alfred suggests that **if targeting CXCR4 works in IPF it may also work in other ILD's**
- **AD-214 is well tolerated and ready to move forward** into multi-dose studies in healthy volunteers and patients
- The **data is supportive of extending dosing interval** to two weekly at least
- **AdAlta approach is methodical and appropriate**
  - **PET imaging strategy** is particularly important as an **innovative way to explore target engagement and mode of action** in diseased tissue
- Key insights anticipated from multidose and early patient studies (in addition to safety):
  - CXCR4 receptor engagement in tissue
  - Nature of the anti-drug antibodies that are expected with a biologic
  - Further characterisation of biomarker responses: CD34+, white cells, SDF-1a

Agenda today

AdAlta

Advantages of amended Phase I design

Preserves original objectives	• Early data on effect of ***elevated CXCR4 on AD-214 distribution and receptor occupancy*** in diseased tissue remains on track for Q3 2021 • Explores potential for ***longer dosing intervals*** • Provides insight to ***mode of action***
Speed	• ***Full Phase II IND ready HV safety package by end 2021***, independent of IPF/ILD recruitment • IPF/ILD ***patient study is easier to recruit***, more flexible • Parallel design enables ***shorter total Phase I program***
New options created	• HV ***safety package*** suitable for ***all intravenous indications*** • IPF/ILD patient study generates preliminary ***safety data in combination with SoC*** • 6 doses over 18 weeks in IPF/ILD study ***may*** provide ***initial indication*** of efficacy • IPF/ILD study may demonstrate distribution, target engagement in ***other CXCR4 indications***
Cost impact	• ***No material impact*** on overall study cost or 2021 cash requirements

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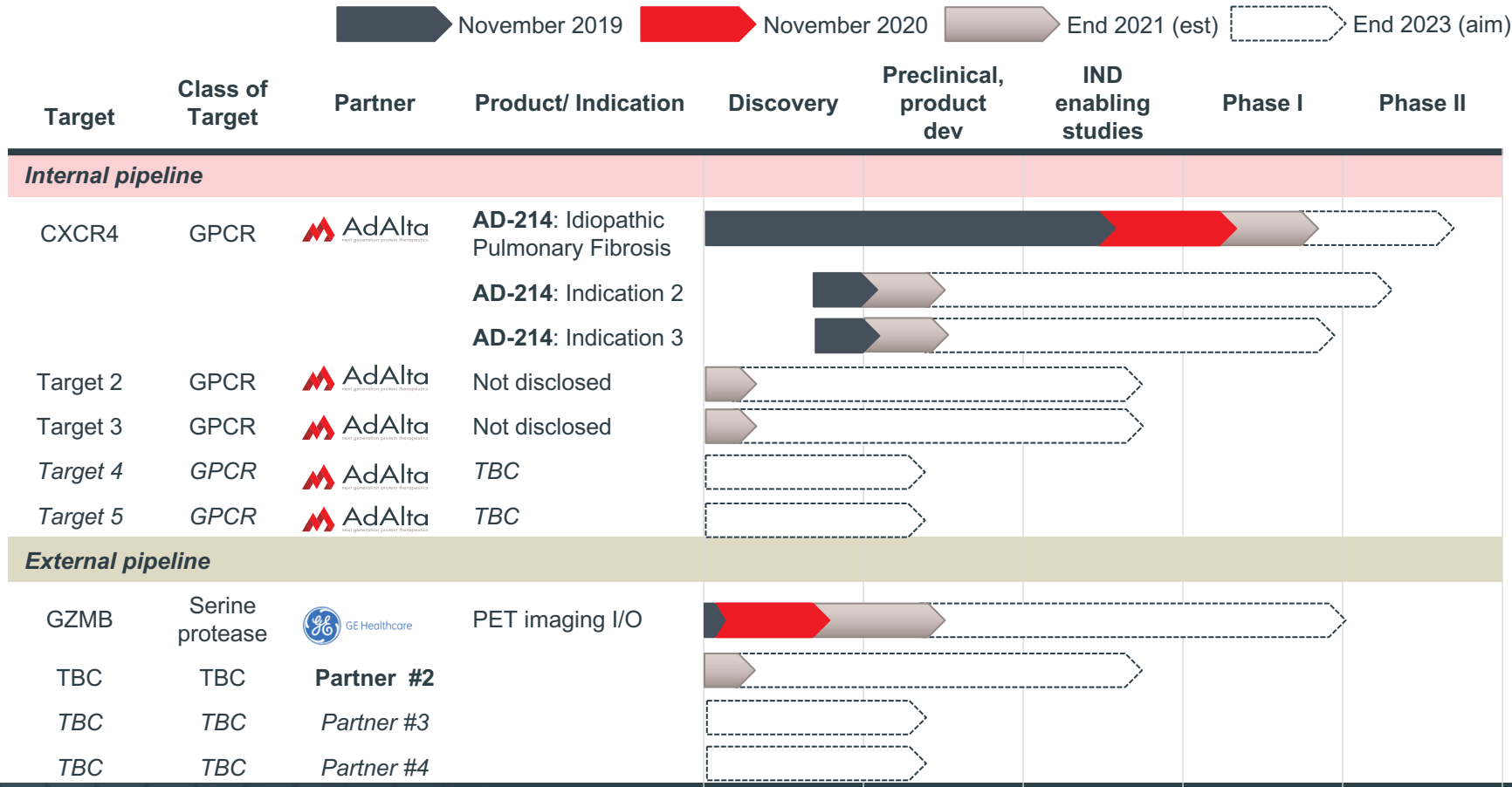
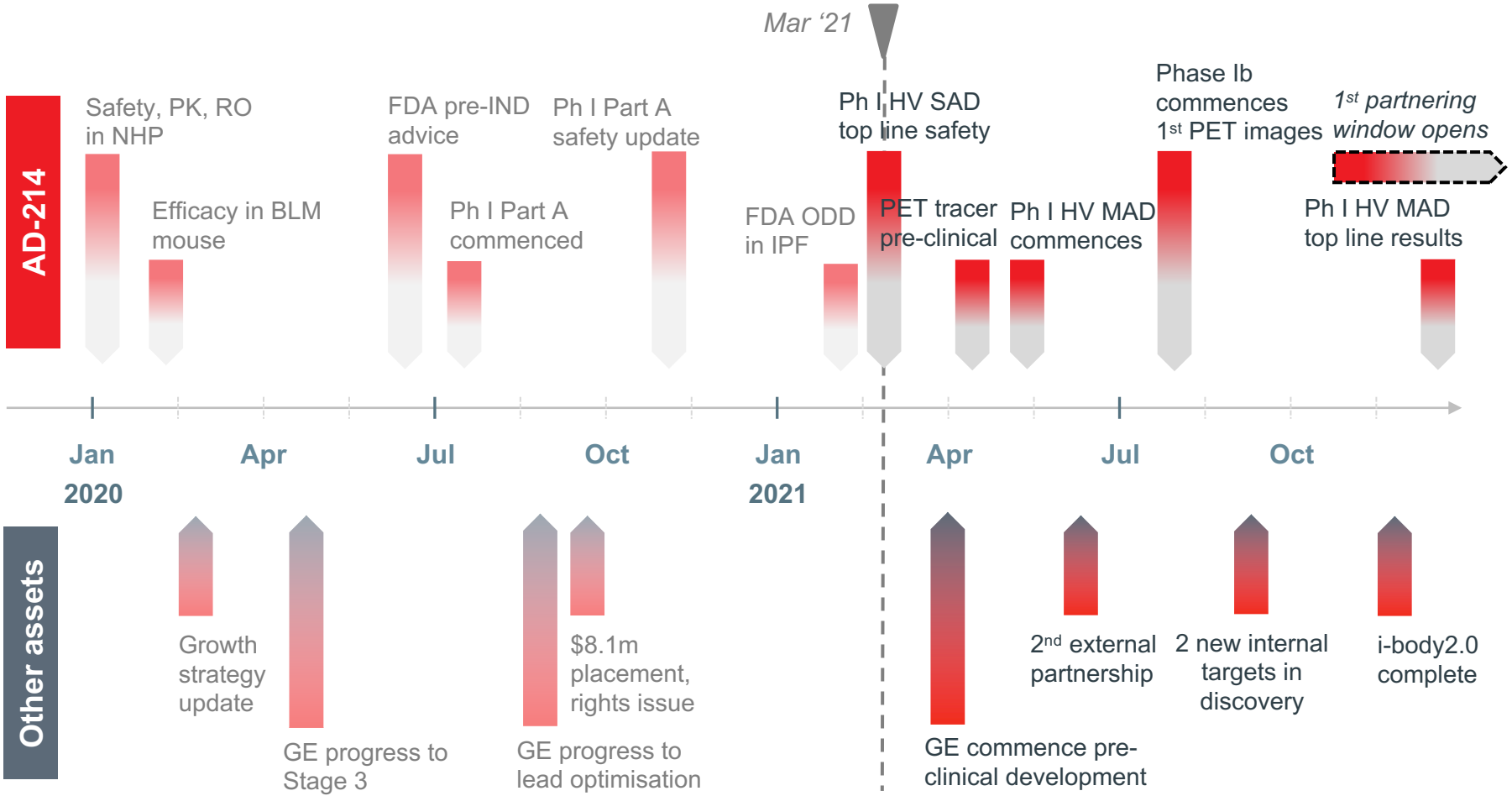
Clinical validation of i-body platform unlocks pipeline expansion opportunities



Target	Class of Target	Partner	Product/ Indication	Discovery	Preclinical, product dev	IND enabling studies	Phase I	Phase II
Internal pipeline								
CXCR4	GPCR	AdAlta	**AD-214**: Idiopathic Pulmonary Fibrosis					
			AD-214: Indication 2					
			AD-214: Indication 3					
Target 2	GPCR	AdAlta	Not disclosed					
Target 3	GPCR	AdAlta	Not disclosed					
Target 4	*GPCR*	AdAlta	*TBC*					
Target 5	*GPCR*	AdAlta	*TBC*					
External pipeline								
GZMB	Serine protease	GE Healthcare	PET imaging I/O					
TBC	TBC	**Partner #2**						
TBC	*TBC*	*Partner #3*						
TBC	*TBC*	*Partner #4*						

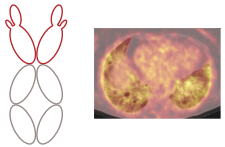
AdAlta

Milestones for remainder of 2021

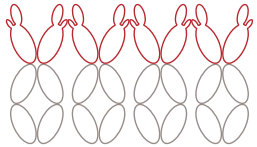


AdAlta (ASX:1AD) investment proposition

- **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**
  - Orphan Drug Designation for US$3 billion idiopathic pulmonary fibrosis (IPF) market
  - Excellent safety profile and sustained high receptor occupancy in Phase I single dose studies
  - Multi-dose studies commencing; PET images in patients Q3-2021; partnering window end of 2021
  - Pre-clinical data available and emerging in multiple fibrotic indications and cancer



- **GE Healthcare: commercial validation of platform**
  - Partner funded discovery program in I/O imaging; progressed to lead optimisation
- **Clear vision for growing existing assets and adding more; A$8m cash balance**
  - AD-214: Phase I patient data, expand indications, partner
  - Internal pipeline: GPCRs in fibrotic, inflammatory disease and cancer (2 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, beginning to realize expansion potential**

AdAlta

AdAlta

next generation protein therapeutics

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