
Avacta®
Avacta Group plc
Preliminary Results
for the Period Ending December 31st, 2022
25th April, 2023

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Avacta Group plc Preliminary Results

for the Period Ending December 31st, 2022

Preliminary Results Highlights

Therapeutics – significant clinical and pre-clinical progress

- Avacta's lead pre|CISION™ drug, AVA6000 – a tumour microenvironment activated form of a chemotherapeutic agent, doxorubicin:
  - Favourable safety profile in the first four patient cohorts.
  - Doxorubicin detected in tumour biopsies at therapeutic levels.
  - Principle of FAP activation of pre|CISION™ drugs confirms tumour targeting potential of the platform.
- The next pre|CISION™ drug candidate, AVA3996, a tumour-targeted proteasome inhibitor based on bortezomib:
  - Pre-clinical data show FAP activated cell killing in in-vitro models.
  - In-vivo models of efficacy show that AVA3996 is as effective as bortezomib and that the drug is better tolerated.
- Good pre-clinical progress in both key research partnerships AffyXell (Daewoong Pharmaceutical) and LG Chem.
- Therapeutics Division relocated to Scale Space, in Imperial College's White City Campus.

Diagnostics – significant progress towards establishing a fully integrated in vitro diagnostics business with first transformational acquisition

- Diagnostics Division initiated a long-term 'buy and build' strategy with a vision to build an in-vitro diagnostics ('IVD') business, with global reach, supporting physicians and broadening access through decentralised testing.
- In October 2022, the Group acquired Launch Diagnostics, the UK's largrest independent IVD distributor serving hospital pathology laboratories in the UK and France for an initial cash consideration of £24 million payable upon completion, in addition to consideration for other short-term non-operating assets of £0.9 million.

Corporate – board further strengthened with drug development expertise

- Dr Christina Coughlin, a medical oncologist and immunologist and Chief Executive Officer of CytoImmune Therapeutics, Inc., appointed as Non-executive Director to the Board of Directors of Avacta in March 2022.

Preliminary Results for the Year Ending 31st December 2022

Income Statement

	2022 (£m)	2021 (£m)
Revenue	**9.65**	**2.94**
Gross profit	**7.24**	**2.02**
Research/Manufacturing costs	(11.10)	(15.62)
S, G & A costs	(11.23)	(8.14)
Adjusted EBITDA	**(15.09)**	**(21.74)**
Amortisation/Depreciation	(8.18)	(2.28)
SBP/Share of AffyXell losses	(9.38)	(5.06)
Operating loss	**(32.65)**	**(29.08)**
Convertible bond	(8.99)	-
Net financial costs	-	(0.11)
Taxation	2.10	2.82
Discontinued operation	0.35	0.06
Retained loss	**(39.19)**	**(26.31)**
Loss per share	15.48p	10.57p

Preliminary Results for the Year Ending 31st December 2022

Operating Segment Analysis

	2022 (£m)				2021 (£m)			
	Dx	Tx	Central	Total	Dx	Tx	Central	Total
Revenue	**4.17**	**5.48**	**-**	**9.65**	**0.78**	**2.16**	**-**	**2.94**
Gross profit	**1.89**	**5.35**	**-**	**7.24**	**0.56**	**1.46**	**-**	**2.02**
Research/Manufacturing costs	(2.31)	(8.79)	-	(11.10)	(5.81)	(9.81)	-	(15.62)
S, G & A costs	(4.71)	(2.40)	(4.12)	(11.23)	(2.89)	(1.90)	(3.35)	(8.14)
Adjusted EBITDA	**(5.13)**	**(5.84)**	**(4.12)**	**(15.09)**	**(8.14)**	**(10.25)**	**(3.35)**	**(21.74)**
Amortisation/Depreciation	(6.88)	(1.28)	(0.02)	(8.18)	(1.32)	(0.95)	(0.01)	(2.28)
SBP/Share of AffyXell losses	(1.44)	(3.86)	(4.08)	(9.38)	(0.99)	(2.98)	(1.09)	(5.06)
Operating loss	**(13.45)**	**(10.98)**	**(8.22)**	**(32.65)**	**(10.45)**	**(14.18)**	**(4.45)**	**(29.08)**

* Excludes Animal Health in both periods

Preliminary Results for the Year Ending 31st December 2022

Cash Flow

	2022 (£m)	2021 (£m)
Cash/short term deposits at 1 January	**26.19**	**47.91**
Operating cash outflows	(16.43)	(20.51)
Investing activities	(25.04)	(1.31)
Financing activities	56.90	0.23
Other	0.16	(0.13)
Cash/short term deposits at 31 December	**41.78**	**26.19**

- Investing activities relates to the Launch acquisition, disposal of Animal Health and capex.
- Financing activities includes the convertible bond £55.0m at 5% discount, placing and open offer less transaction costs.
- Cash at 31 March 2023 is circa £39.0 million with benefit post-year end of receiving the R&D tax credits refund from FY21 of £2.8 million.

Preliminary Results for the Year Ending 31st December 2022

Balance Sheet

	2022 (£m)	2021 (£m)
Non-current assets	37.10	12.27
Current assets (exc. cash/deposits)	13.77	7.26
Cash/deposits	41.78	26.19
Assets held for sale	-	1.28
Current liabilities	(14.00)	(4.37)
Non-current liabilities	(60.21)	(1.41)
Net assets	**18.44**	**41.22**

- Non-current assets include PPE, IFRS16 leases re Avacta facilities, goodwill on the Launch acquisition and investment in AffyXell.
- Current assets include FY21 and FY22 R&D tax credit and Launch debtors/inventories
- Liabilities (current & non-current) include the following:
  - IFRS 16 lease liabilities of £5.22 million.
  - Convertible bond – debt value £18.73 million
  - Convertible bond – derivative value £39.10 million
- Convertible bond outstanding following 2nd amortisation on 21 April is now down to £46.8 million.

Avacta Therapeutics

Business Update

Avacta Therapeutics

Improving cancer patients' lives through innovation and partnership

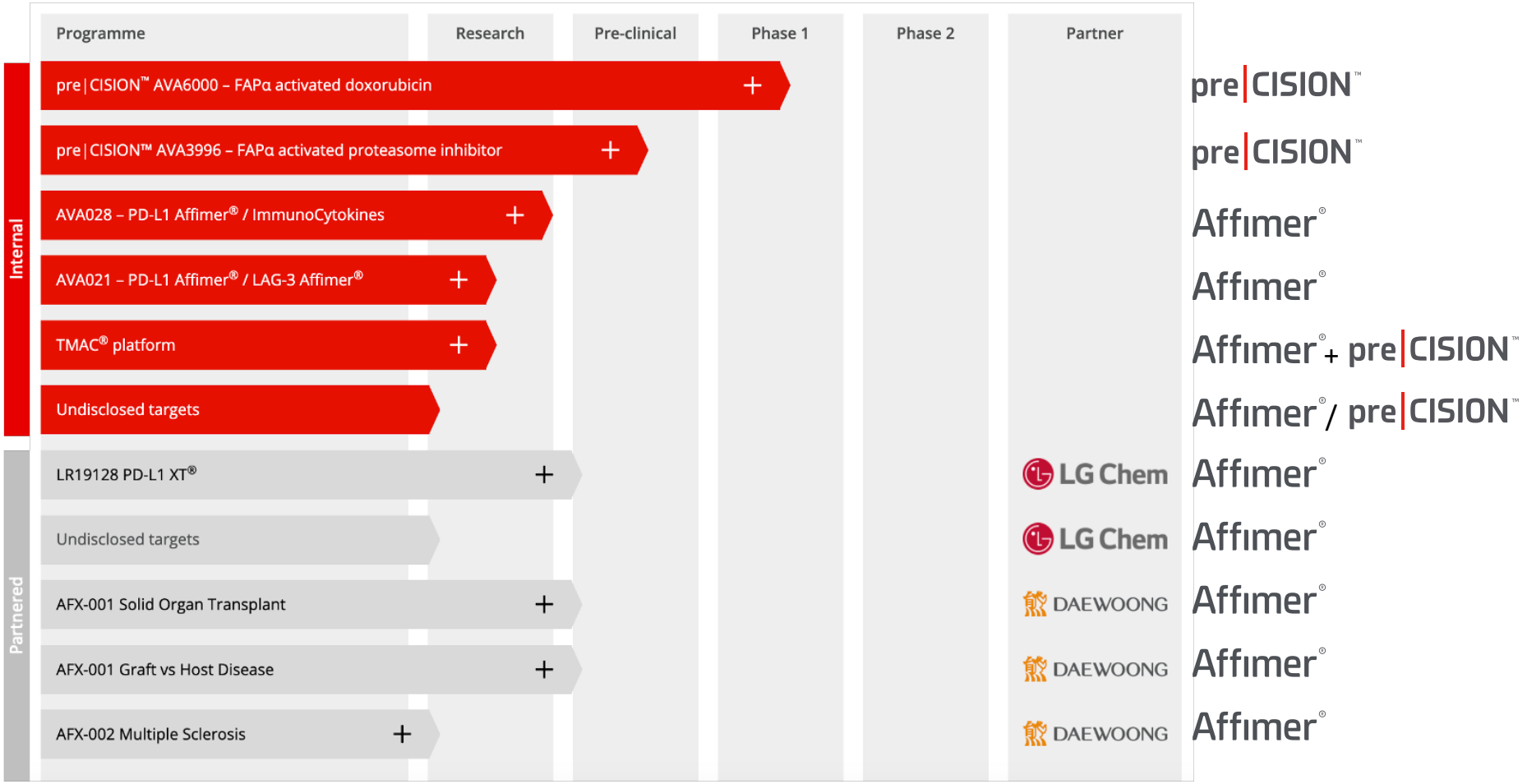
VISION

Our vision is to deliver innovative oncology drugs that transform treatment outcomes to improve cancer patients' lives.

STRATEGY

- Use our proprietary pre|CISION™ and Affimer® platforms to develop best-in-class and first-in-class cancer therapies.
- Grow our clinical pipeline alongside selective and focused out-licensing.
- Combine our in-house drug development expertise with a focused partnership strategy.

Avacta Therapeutics Pipeline – 2023



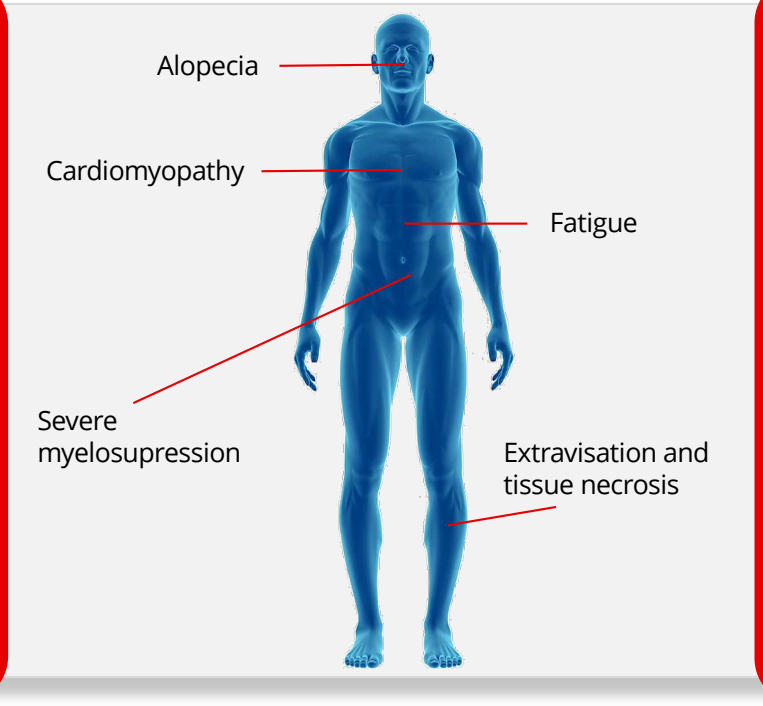
pre|CISION™ Targeting Payloads to the Tumour

Reducing systemic toxicities of chemotherapies and improving tolerability for patients through tumour-specific activation

The Problem

- Chemotherapy, cytotoxic agents and immunotherapies are not tumour selective.
- Systemic toxicities and tolerability for patients limit the therapeutic index of most oncology drugs.
- There is an urgent unmet need to differentiate between tumour and normal cells.

Common Doxorubicin Toxicities



pre|CISION™

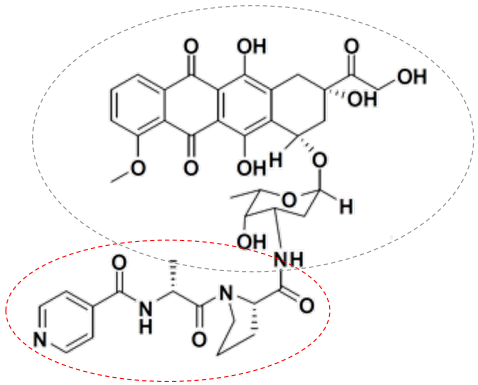
- Targets the tumour tissue and limits systemic exposure.
- Selectively activated in the tumour microenvironment by an enzyme that is in high concentration in most solid tumours.
- Designed to enhance safety and tolerability and increase efficacy.

AVA6000: Targeting Doxorubicin to the Tumour

Reducing the side-effects of doxorubicin through tumour-specific activation using the pre|CISION™ technology

AVA6000

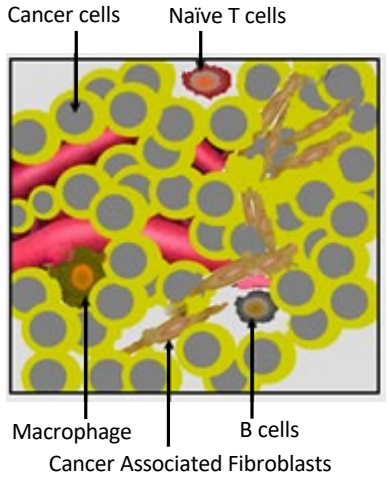
Doxorubicin



pre|CISION™

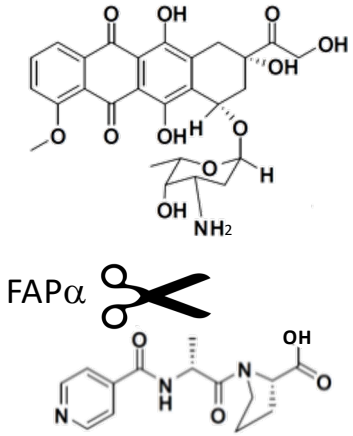
Prevented from entering cells by pre|CISION modification

Tumour Microenvironment



FAPα +ve fibroblasts and cancer cells

Release of Active Doxorubicin



FAP mediated release of doxorubicin

AVA6000: Ongoing Phase 1 Dose Escalation & Expansion Trial

Phase 1a Dose Escalation

Primary Objectives

- Safety and tolerability of AVA6000.
- Maximum tolerated dose and/or recommended phase 2 dose of AVA6000.

Patient Population

- Locally advanced or metastatic selected solid tumours.
- 20-30 patients.

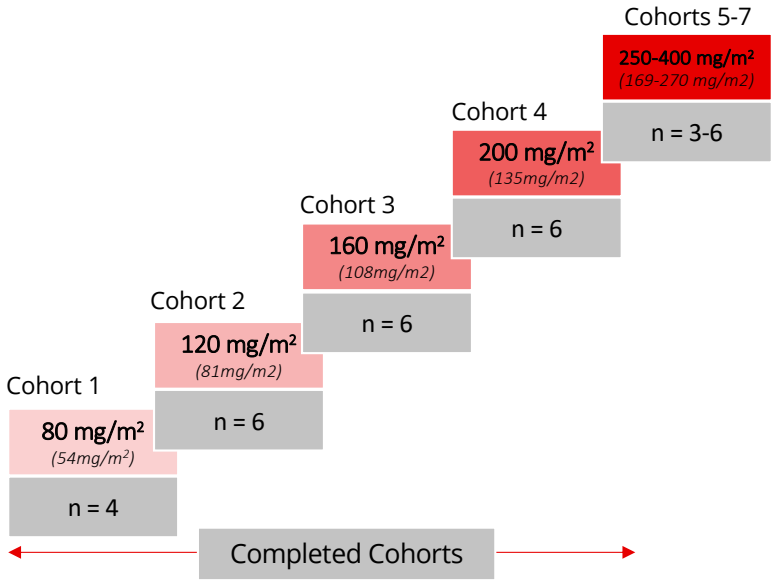
Endpoints

- Dose limiting toxicities, safety, tolerability & cardiac safety.
- Pharmacokinetic profiles for cycles 1 & 2.
- Optional biopsies (AVA6000/Dox levels).
- Tumour assessments.

Centres

- 5 UK (open) & 2 US (opened post-period end)

AVA6000 Dose Regimen - 3 weekly cycles *(Doxorubicin Equivalent Dose)*



"n" = number of patients in cohort

Summary of ALS-6000-101 Phase I Dose Escalation Data

Positive safety profile and biopsies confirm release of doxorubicin in the tumour tissue at therapeutic levels

- 22 patients with a range of solid tumours dosed across four dose escalation cohorts.
- Currently dosing patients in the fifth cohort at 250mg/m^2.

Safety and Tolerability

- AVA6000 is well tolerated across first four cohorts.
- Marked reduction in the incidence and severity of the usual doxorubicin related toxicities (alopecia, nausea, myelosuppression, mucositis) including the most serious (neutropenia, thrombocytopenia, anaemia).
- Despite administering the equivalent of more than double the normal dose of doxorubicin to patients in cohort 4, the typical drug-related cardiotoxicity of doxorubicin has not been observed.

Biopsy Analysis

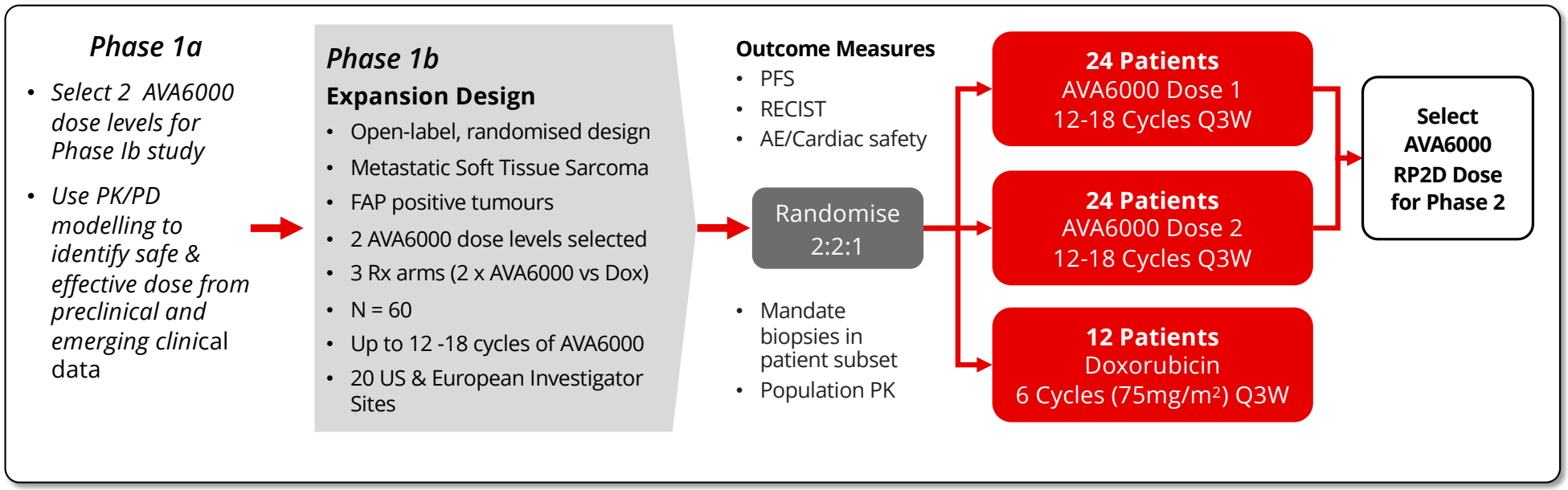
- Analysis of tumour biopsies taken from 6 patients confirms pre|CISION™ can deliver therapeutically significant levels of doxorubicin to tumour tissue compared to systemic levels at same timepoint.

AVA6000: Phase Ib Study

Clinical development in Soft-Tissue Sarcoma (Phase 1 to 2)

Development Rationale in Soft Tissue Sarcoma (STS)

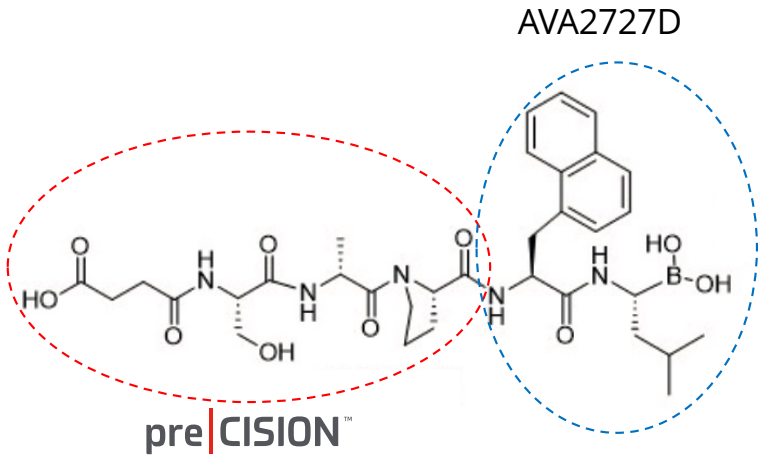
- Advanced, Metastatic STS tumours
- Doxorubicin is the only therapy indicated for first-line monotherapy in advanced STS
- No current or near future competition for doxorubicin in 1st line STS
- Conventional doxorubicin has marginal efficacy (18% ORR; 6mth PFS) & Rx limitation due to cumulative dose limit (450mg/m^2 – 6 cycles maximum)
- AVA6000 has potential to safely increase Rx duration beyond 6 cycles (18 weeks) by x2-3 times (12-18 cycles – 36-54 weeks) with increased efficacy



Pre-clinical Programmes

AVA3996: A Novel Tumour Targeted Proteasome Inhibitor

- The “proteasome” is the cell’s “garbage disposal” system that breaks down protein waste.
- A working proteasomal degradation pathway (“garbage disposal”) is essential for a cell to survive.
- Inhibiting the proteasome (turning off the “garbage disposal” system) leads to cell death of many types of cells including cancer cells.
- AVA3996 is a pre|CISION™ proteasome inhibitor. The inhibitor itself is referred to as AVA2727D.



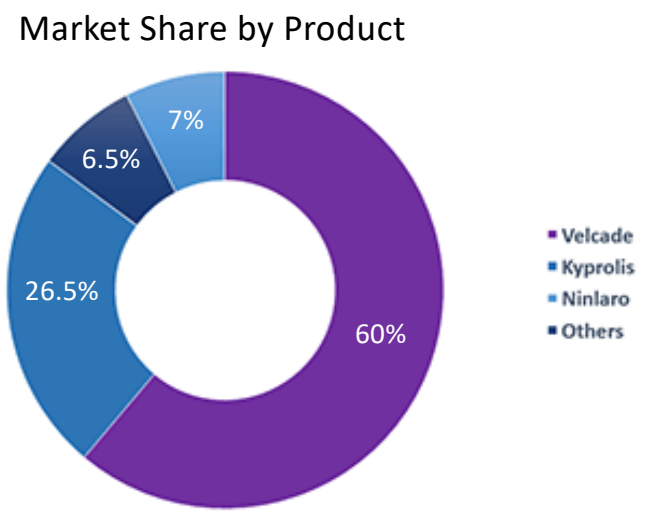
AVA3996 pre|CISION™ Proteasome Inhibitor

Proteasome Inhibitor Market

- The **global proteasome inhibitors market** is expected to grow at a CAGR of 8.4% (2023-2028) to reach nearly USD 2.3 billion by 2026[1].
- Proteasome inhibitors have severe dose limiting toxicities which have restricted their approval.
- Three are approved for treating multiple myeloma:
  - Bortezomib (*Velcade*) was approved in 2003. This was the first proteasome inhibitor approved for use in the U.S. AVA2727D is very similar but not identical to bortezomib.
  - Carfilzomib (*Kyprolis*) was approved by the FDA for relapsed and refractory multiple myeloma in 2012.
  - Ixazomib (*Ninlaro*) was approved by the FDA in 2015 for use in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma after at least one prior therapy.

1. (https://www.expertmarketresearch.com/reports/proteasome-inhibitors-market)

Global Proteasome Inhibitors Market 2022 (~$1.7billion)

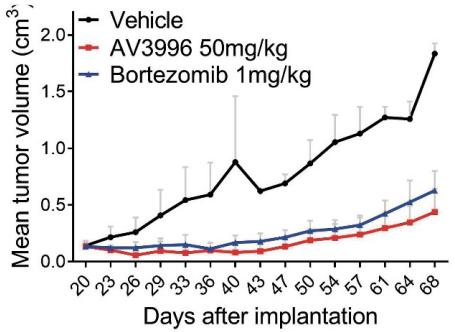


Source: https://www.expertmarketresearch.com/reports/proteasome-inhibitors-market

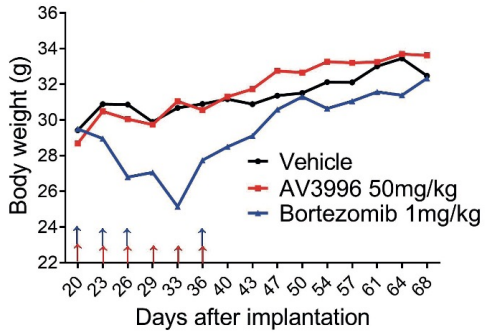
In-vivo Efficacy in Multiple Tumour Models

Melonoma Model

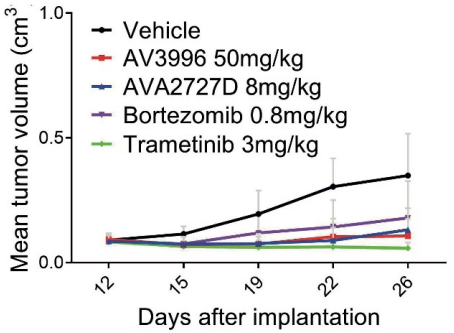
Tumour growth inhibition: melanoma PDX model



Body weight: melanoma PDX model



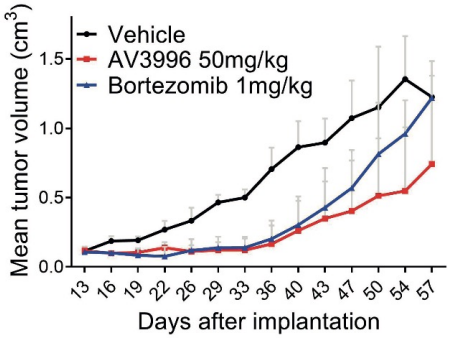
Tumour growth inhibition: melanoma PDX model



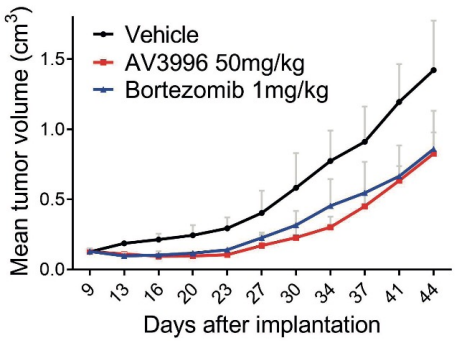
Key Takeaways

- AVA3996 is as effective in these different mouse PDX models as bortezomib and, in the case of the melanoma model, as trametinib.
- Mice did not show the same toxicities when treated with AVA3996 as when they were treated with 1mg/kg bortezomib.

Tumour growth inhibition: sarcoma PDX model



Tumour growth inhibition: colorectal PDX model

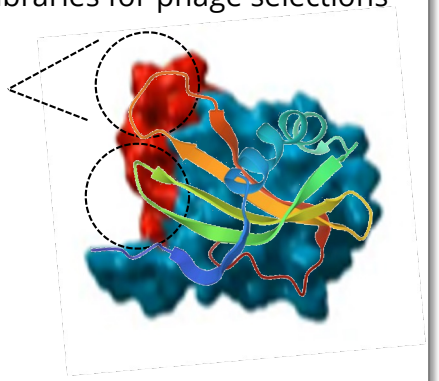


Affimer® Next-generation Biotherapeutics

What is an Affimer®?

Based on a naturally occurring human protein (stefin A) and engineered to display two loops that create an antigen binding surface

Variable loop regions of 9 amino acids each create a target recognition surface and can be randomised to create very large (10^{10}) libraries for phage selections



Affimer®

Technical Benefits

Smaller (14 kD), simpler and more robust, soluble and stable than antibodies

High affinity Affimer® candidates generated for new targets rapidly

Flexible formatting for multi-specifics, agonism, drug conjugates

High expression levels in a range of cells and tissues

Fully human: lower immunogenicity risk

Commercial Advantages

Proprietary and unencumbered IP

Freedom to operate where there is antibody-based IP

Differentiated Biotherapies

Flexible solutions for **difficult-to-drug** targets **eg GPCRs**

Exquisitely selective for target antigen

Building blocks for **developable multi-specific** formats

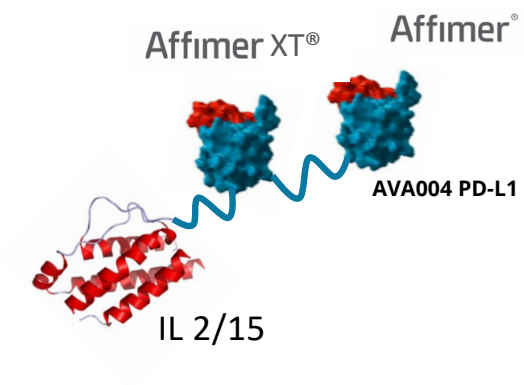
(Proof-of-concept multi-specific Affimers (LG Chem collaboration PD-L1 / XT) have demonstrated the developability of the platform)

Half-life extension capability and tunable pharmacokinetics

Affimer® Internal Research Programmes

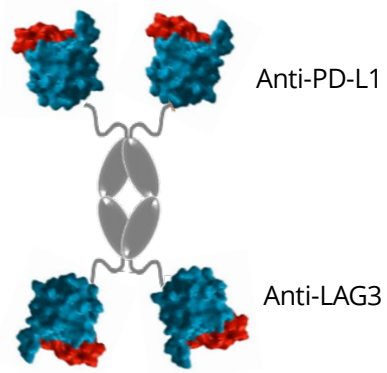
AVA028 PDL1/Cytokine Bispecific

- Most patients either do not respond to immune checkpoint blockade or will acquire resistance.
- Next generation immunotherapies aim to overcome this lack of response with combination strategies aimed at increasing response to checkpoint blockade.
- Avacta's Immunocytokine approach combines immune checkpoint blockade with cytokine driven T cell stimulation.



AVA021 Next Generation Multispecific Immunotherapies

- Exhausted T cells have a reduced ability to proliferate and have high-level expression of inhibitory receptors, programmed cell death-1(PD-1) and lymphocyte-activation gene 3 (LAG-3)
- LAG3 is involved in immune tolerance and is associated with poor clinical outcomes.
- Preclinically, combination of anti-LAG-3 and anti-PD-(L)1 antibodies has shown synergistic effects vs blocking either one alone.
- AVA021 is an Affimer-based PDL1/LAG3 bispecific immunotherapy.



Tumour Microenvironment Activated Drug Conjugates

- Cytotoxin linked to immunotherapy by pre|CISION™ linker.
- Cytotoxin released in the TME/stroma by FAP.
- Potential for synergistic action of pro-inflammatory cytotoxin and immunotherapy.

Key Partnerships

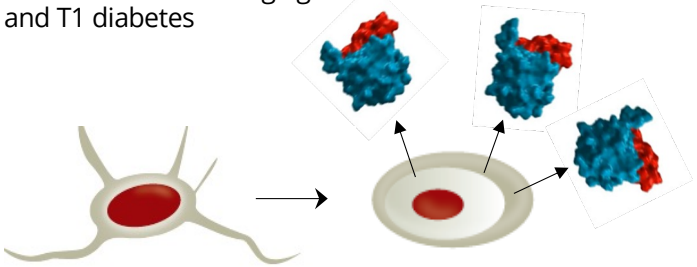
AffyXell – Joint Venture in the Cell & Gene Therapy

AffyXell THERAPEUTICS

A joint venture in South Korea with Daewoong Pharmaceutical to develop engineered mesenchymal stem cells that express and secrete immuno-modulatory Affimer molecules to treat autoimmune diseases

Next-generation Stem Cell Therapies

- Renewable "off the shelf" mesenchymal stem cells
- AFX001: MSC secreting anti-CD40L Affimer for use in GvHD
- AFX002: MSC secreting agonist Affimer for use in MS and T1 diabetes



COMPANY TECHNOLOGY PIPELINES AffyXell THERAPEUTICS INVESTORS & MEDIA CONTACT KR | EN

Development stage

Product Candidate	Target Indication	Discovery	Pre-clinical	Phase1	Phase2	Phase3
AFX-001	SOT					
	GvHD					
AFX-002	MS					

During the reporting period:

- Entered into collaborations with Biocytogen, a Chinese company specialising in developing new biological drugs, and with the Korea Non-Clinical Technology Solution Center ('KNTSC').
- The strategic partnership with GenScript ProBio, a leading biopharmaceutical manufacturer was expanded.
- Successfully completed a funding round to advance its lead mesenchymal stem cell ('MSC') programme towards the clinic, and to develop its wider pre-clinical pipeline of cell therapies.
- Avacta's shareholding in AffyXell increased to 19% following the triggering of a milestone equity payment of £3.60 million.

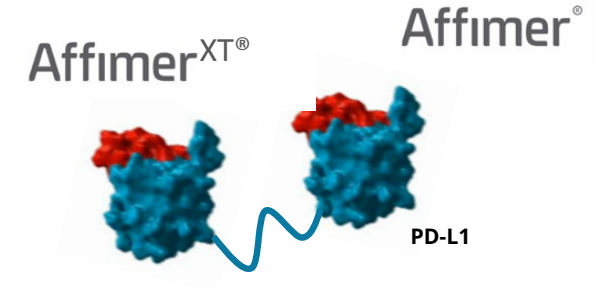
Data will be presented at International Society for Cell & Gene Therapy, May 2023 (AffyXell and Avacta) https://www.isctglobal.org/isct2023/home

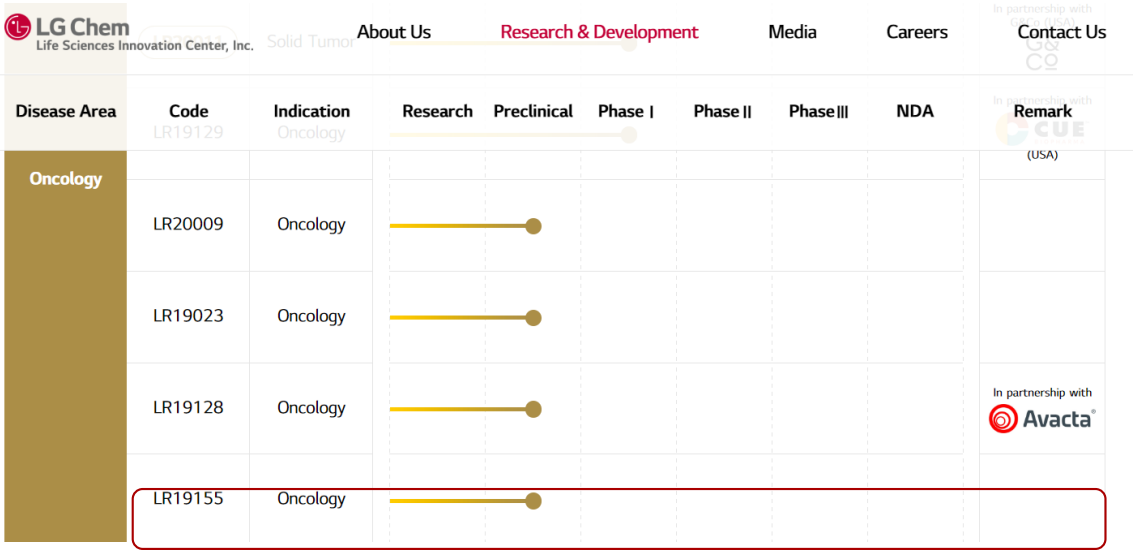
LG Chem – Multi-target Partnership

A multi-target development partnership and licensing deal worth up to $310 million with a focus on oncology and inflammatory diseases

PDL1/XT Antagonist

- PD1/PDL1 axis Affimer inhibitor
- Half-life extension using Affimer XT® a human serum albumin binder
- Small size potentially leads to better tumour penetration





During the reporting period;

- LG Chem Life Sciences ('LG Chem'), the life sciences division of the South Korean LG Group, exercised its renewal option as part of the ongoing collaboration with Avacta, triggering a licence renewal fee payment to Avacta of $2 million.

Avacta Diagnostics

Business Update

Avacta Diagnostics: M&A Led Growth Strategy

VISION

Build an integrated and differentiated in-vitro diagnostics (IVD) business with global reach serving professionals and consumers.

MISSION

Innovate to make market leading diagnostic solutions available to all, to inform treatment and monitor health and fitness.

Markets, Applications, Customers and the DX Value Chain

Supporting Healthcare Professionals | **Improving Access**

Centralised Testing		Decentralised Testing
Pathology Laboratory	Rapid PoC Tests	Self-sampling

LAUNCH

Diagnostics Value Chain

Research	Product Development	Manufacturing	Sales and Marketing	Logistics and Distribution
• Affimer® reagents • Sampling devices • Software/apps • IP	• Market led • Lateral flow tests • IP	• High volume • High quality • Competitive costs	• Lead generation • Sales channel management • Market intelligence	**Commercial and Technical Support**

Launch Diagnostics: Supporting Healthcare Professionals

Launch

- Leading UK IVD distributor with a growing business in France.
- Established for over 30 years.
- Very strong relationship with NHS.

Rationale

Acquisition of a profitable distribution channel into centralised pathology laboratories with the market knowledge to help drive future strategy and with good opportunities for growth.

Launch Diagnostics

Key Facts

- Founded in 1990 and headquartered in UK.
- Launch provides immunodiagnostic and molecular test products, technical support and maintenance to healthcare providers in the UK, France, Belgium and Luxemburg and ROI.
- Customers include both public and private sector (e.g. hospitals, clinical trial units, cancer centres, commercial laboratories).
- Long-established and experienced team with an outstanding reputation in the industry for customer service.
- Sales delivered through tenders, contracts such as long term and exclusive Managed Equipment Services with global manufacturers, and annual quotations.

Launch by Numbers

- FY21 £14.17M core, non-COVID related business.
  - Total FY21 revenue £32.75M.
  - £23.85M UK and £8.90M France/Benelux.
  - Gross margin on sales FY19-21 44-50%.
  - £8.52M adjusted* EBITDA FY21.
- FY22 £16.5M non-COVID revenue.
- Over 4,000 products from 31 suppliers.
- 501 active customers (UK 356, France/Belux/ROI 145).
- Typically on 3-5 year contracts and c.95% repeat business.
- c.70 FTEs (60% commercial, 40% technical).
- 17,295 ft^2 offices and warehouse facilities in UK.
- 230 m^2 logistics facilities in Houlle, Northern France.

* Adjusted to a market rate Managing Director salary and removal of non-recurring professional fees.

Launch Diagnostics: Growth Opportunities

Opportunities for growth in sales and margin through geographical expansion, cross-selling to customers gained during the pandemic and expansion of product range

Investment in Sales and Marketing

- Investment in sales and marketing team.
- Cross-selling of non-COVID products into the recently expanded installed base of PCR equipment post-COVID.

Short Term

Portfolio Expansion

- Expansion of centralised and decentralized testing product portfolio.
- e.g. New automated system for autoimmune and allergy testing (HOB).

Medium Term

Geographical Expansion

- Investment to expand commercial, logistics and support teams to expand into German market over a 3 year period.
- New logistics site already established in northern France.

Long Term

Summary

Principle of tumour targeting through FAP activation of pre|CISION™ mdified chemotherapy confirmed in AVA6000 phase 1 study.

AVA3996, an FAP-activated proteasome inhibitor, showing positive pre-clinical data; now in IND enabling studies with FIH expected 2024.

Launch Diagnostics: First acquisition in the diagnostics M&A-led growth strategy and a financially transformative deal for Avacta Diagnostics.

October 2022 fund raise provides balance sheet flexibility for focused M&A led growth in diagnostics and achievement of key milestones in therapeutics.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