



Affimer[®]
pre|CISION[™]

Interim Results for the 6 Months Period Ending 30th June 2021

September 30th, 2021

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Introduction

Today's Presentation Team



Dr Alastair Smith, CEO

- Over 15 years experience as a life sciences public company CEO.
- Science background with 13 years in academia – established a leading UK biophysics group.
- Founded Avacta in 2006.
- World class scientific and technical knowledge with a highly commercial mindset.



Tony Gardiner, CFO

- Over 20 years senior financial and operational experience across multiple sectors.
- 4 years as CFO of AIM listed Fusion IP plc, 5 years as Finance Director of Aedas/AHR Architects.
- Joined Avacta in 2016.



*Shaping the future of medicine with powerful
therapeutic and diagnostic platforms*

Affimer[®]

pre|CISION[™]



LSE: AVCT

Therapeutics Division

- Clinical stage oncology drug company based in Cambridge and London, UK
- R&D Centre: 35 (inc 20 PhDs) scientists/technicians
- Clinical Development Group established including Translational Sciences, CMC, Clinical Operations
- In-house pre-clinical and clinical pipeline of novel cancer therapies based on the Affimer and preCISION technologies
- Global partnerships (oncology, autoimmune, cell and gene therapy)

Affimer®

pre|CISION™



Diagnostics Division

- In-vitro diagnostics company based in Wetherby, UK
- R&D Centre and plc Headquarters
- 49 (inc 22 PhDs) scientists/technicians
- First Affimer IVD launched: AffiDX® SARS-CoV-2 antigen lateral flow test
- In-house IVD product pipeline
- Global technology evaluations and partnerships.

Affimer®

*New London Global HQ
for Therapeutics Division
Scale Space, White City*





**Interim Results for the Period
Ended 30th June 2021**

Interim Results for the Period Ending 30th June 2021 : Income Statement

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	6 months ended 30 June 2021 (£m)	6 months ended 30 June 2020 (£m)	12 months ended 31 December 2020 (£m)
Revenue	2.32	1.81	3.64
Gross profit	1.51	1.22	2.18
Gross margin	65%	68%	60%
R&D & Amortisation costs	(6.70)	(4.24)	(10.19)
Admin, Dep'n & SBP costs	(6.15)	(5.08)	(13.28)
Operating loss	(11.34)	(8.10)	(21.29)
Financial income/(costs)	(0.06)	(0.01)	(0.05)
Taxation	1.20	1.12	2.45
Retained loss	(10.20)	(6.99)	(18.89)
Loss per share	4.09p	3.74p	8.37p

Interim Results for the Period Ending 30th June 2021 : Cash Flow and Balance Sheet

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	30 th June 2021 (£m)	30 th June 2020 (£m)	31 st Dec 2020
Operating activities	(8.82)	(5.48)	(14.07)
Working capital	(1.38)	1.08	0.72
Tax and interest	(0.05)	(0.01)	2.70
Investment (exc. deposits)	(0.80)	(1.02)	(1.88)
Financing	0.11	51.09	51.65
Net cash (outflow)/inflow	(10.94)	45.66	39.12
Cash and deposits	36.97	54.45	47.91
PPE (inc. lease assets)	4.86	2.70	4.79
Intangible assets	9.07	12.02	9.42
Other net assets/(liabilities)	2.53	2.26	(0.19)
Net assets	53.43	71.43	61.93

Innovative Cancer Therapies

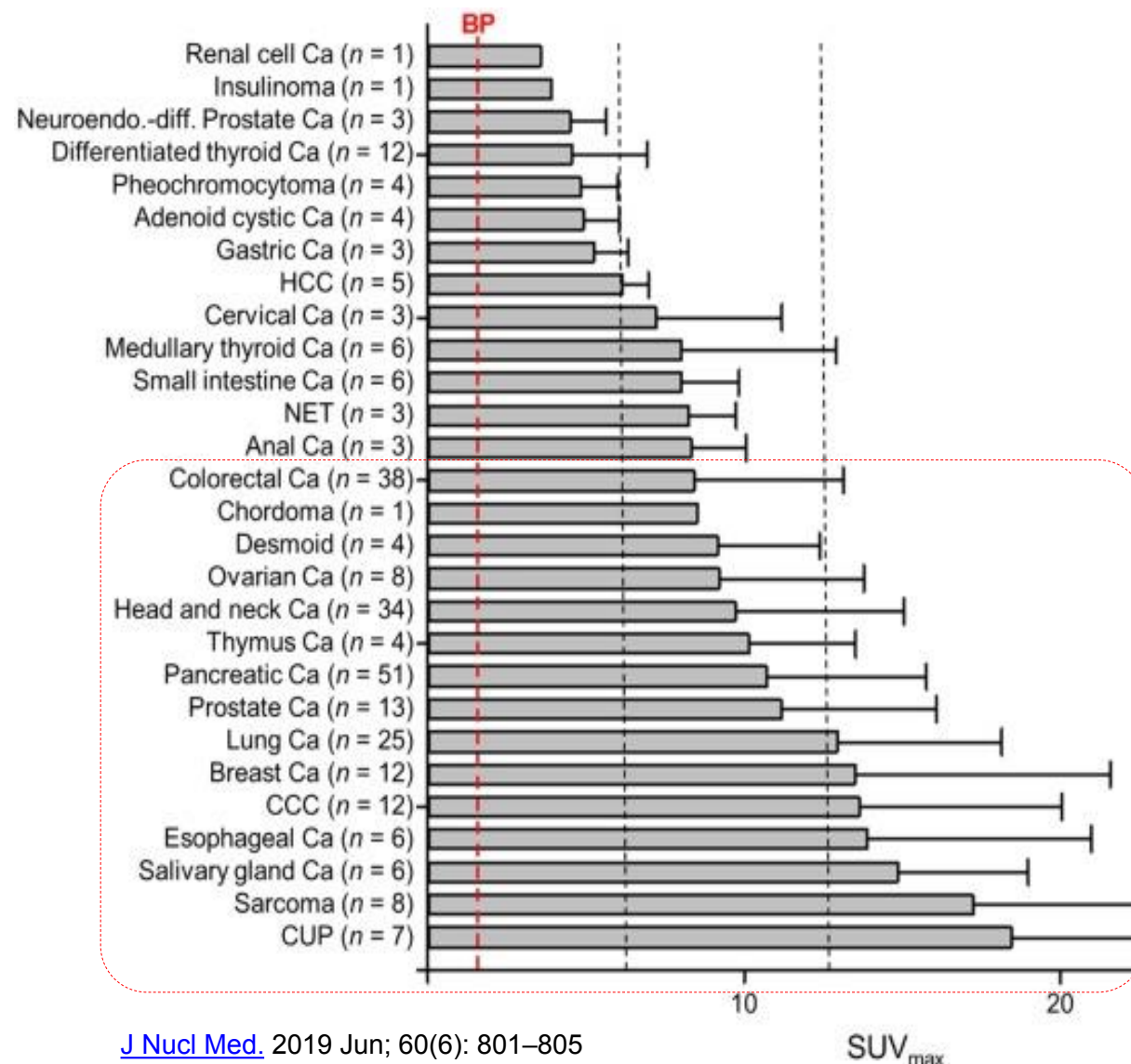


What is pre|CISION™?

- pre|CISION is a **highly specific** substrate for **fibroblast activation protein- α (FAP α)**, an **extracellular enzyme** that is **highly upregulated in most solid tumours**.
- pre|CISION prevents chemotoxins from entering cells **rendering them inert until it is removed in the tumour microenvironment** by FAP.
- pre|CISION can also be incorporated into a **drug conjugate linker for release of the targeted warhead in the tumour microenvironment**.
- pre|CISION exclusively licensed from Tufts University Medical School.



"FAP High" tumours



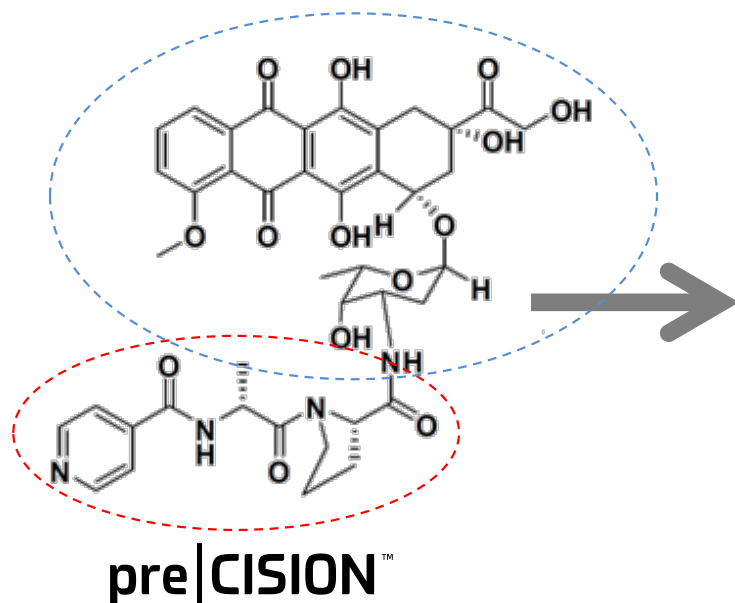
[J Nucl Med.](#) 2019 Jun; 60(6): 801–805

SUV_{max}

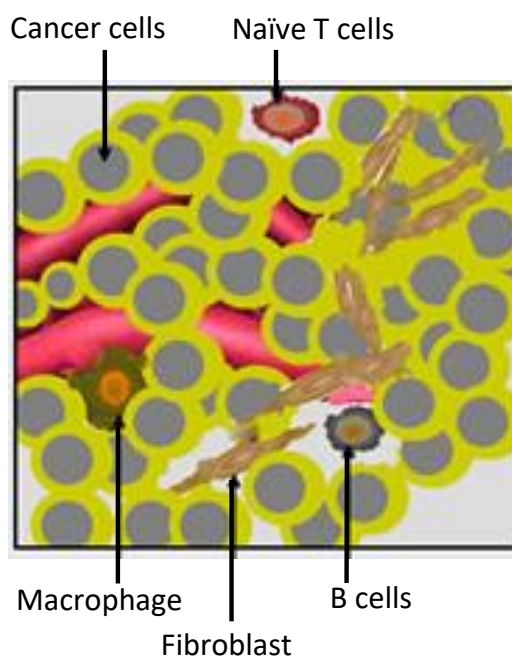
The pre|CISION™ Platform in Detail

Reducing the side-effects of chemotherapy by tumour-specific activation

AVA6000

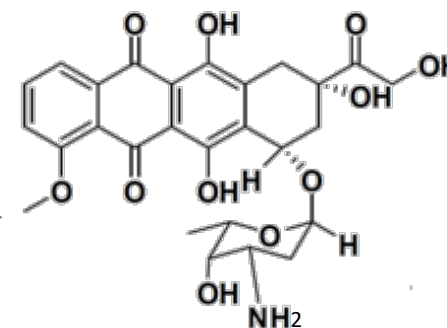
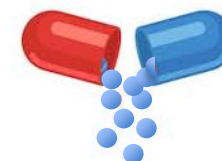


Tumour Microenvironment

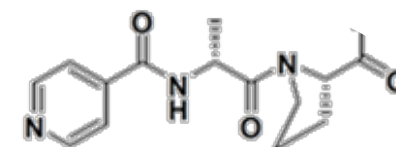


FAPα +ve fibroblasts and cancer cells

Active Doxorubicin



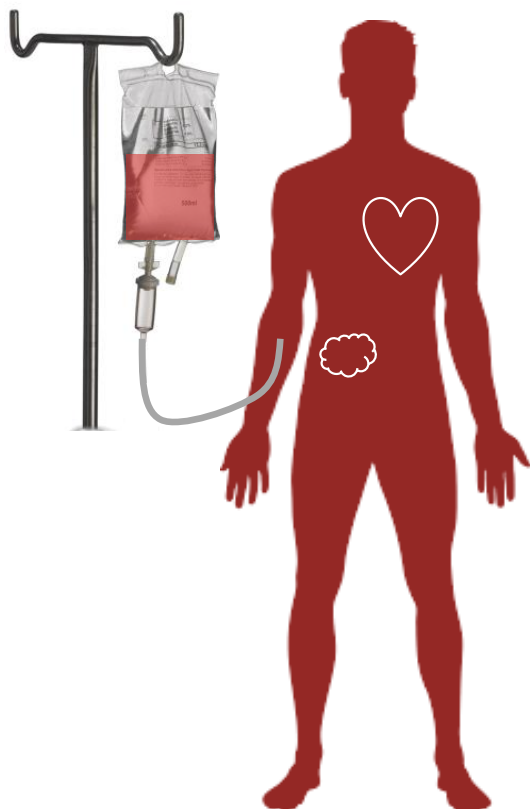
FAPα



The Benefit to Patients

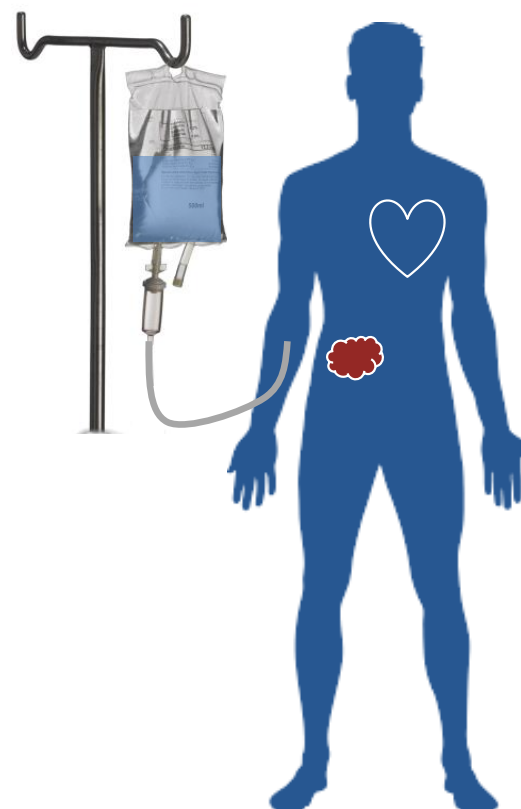
Reducing the side-effects of chemotherapy by tumour-specific activation

Standard Chemo Systemic Dosing



All organs equally exposed to chemotherapy-
leads to poor tolerability for patients.

pre|CISION Prodrug Systemic Dosing



The prodrug is expected to be distributed around the body with
active chemotherapy expected to be released by FAP
predominantly in the tumour with lower exposure to healthy
tissue compared to the conventional chemotherapy.

AVA6000 addresses the safety issues of a \$1bn generic chemotherapy

Background

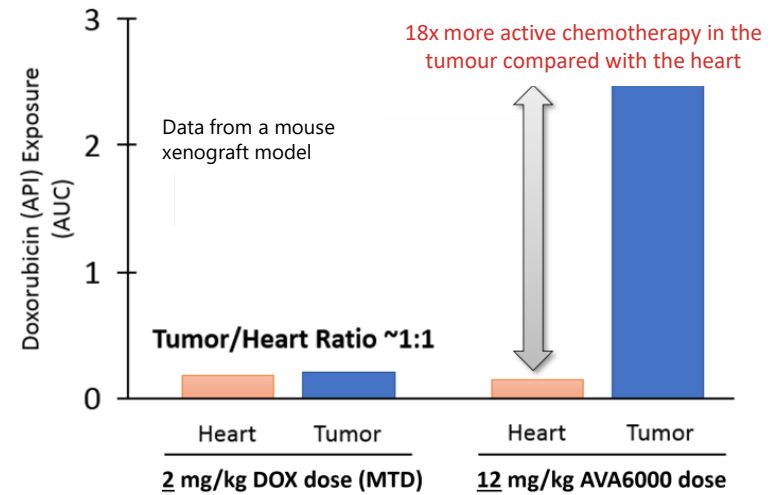
Doxorubicin has been a standard of care treatment for advanced soft tissue sarcoma (ASTS) for 40 years.

Its use is limited by serious dose limiting toxicities such as cardio-toxicity and myelosuppression.

Nevertheless, the global market for this generic drug is \$1bn.

Improved safety could permit many more cycles of treatment per patient at the same dosing level.

Targeting of Drug to Tumour Spares Heart Tissue



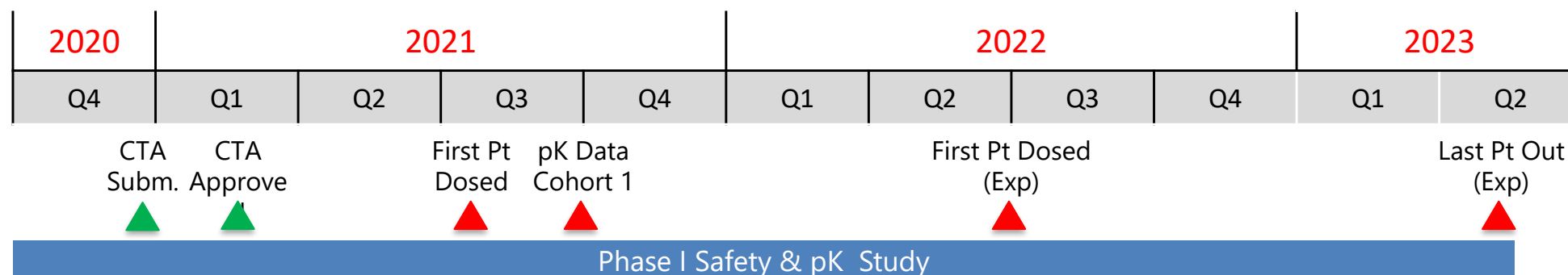
AVA6000 Disease Positioning and Market Opportunity

There are several areas where AVA6000 could potentially be positioned clinically:

- As a monotherapy in specific metastatic tumours where anthracycline monotherapy is currently a standard of care treatment option and/or metastatic tumours that are known to be FAP positive *e.g.*, soft-tissue sarcoma.
- In combination with standard of care treatment in specific metastatic tumours *e.g.*, in combination with taxanes in metastatic Triple Negative Breast Cancer.

For three indications only (ASTS, breast and ovarian cancer) peak sales for a safer/more efficacious form of dox in the US/EU alone is estimated to be **\$1.5bn* pa with a 5-10% royalty to Avacta plus development milestones in near term** (Commercial Evaluation: AVA6000, Globe Life Sciences, March 2020).

AVA6000 Phase I Design and Timeline



Approvals & Study Set Up

Phase Ia - Dose Escalation

Phase Ib - Dose Expansion

Update

- Up to six sites in UK (Leeds, The Royal Marsden, The Christie, Newcastle, The Beatson, Sheffield)
- Starting dose 80mg/m² AVA6000
- Equivalent to 54mg/m² Doxorubicin
- First patient in 11th August at The Royal Marsden
- Other sites coming on line

Phase 1a

- **Objective:** Assess safety and tolerability of AVA6000; determine MTD and/or recommended dose for further development
- Approximately 4 Cohorts to achieve MTD
- **15 to 20 patients**
- **Patient Population:** Locally advanced and/or metastatic pancreatic, colorectal, non-small cell lung, breast, head and neck (SCCHN), soft tissue sarcoma, ovarian and bladder cancer

Phase 1b

- **Objective:** confirm safety and tolerability of AVA6000 at the MTD (or recommended dose) determined in Part 1; explore preliminary anti-tumour activity
- Up to 3 cohorts & 15-20 patients/cohort
- **Patient Population:** selected on the basis of Part 1 data.

MTD - Maximum Tolerated Dose

The Wider pre|CISION™ Pro-drug Opportunity

pre|CISION™ can be widely applied to a range of other chemotherapies in a market worth \$56.5B with CAGR of 11.50% driven by increased cancer detection rates

Example: Velcade

- Bortezomib (Velcade, Takeda Pharmaceuticals) had annual sales of \$1.2bn (2018)
- **BUT – approval limited to multiple myeloma because of dose limiting toxicities,**
- **AND - coming off patent by 2022.**
- Pre-clinical development of AVA3996 pro-velcade will be restarted using placing proceeds.

Example: Taxanes

- Taxanes, such as the generic Paclitaxel, are used to treat a range of cancers such as prostate, breast and cervical.
- Paclitaxel has global sales of \$2.96bn (2018) and is expected to generate revenue of \$6.63bn by end of 2025.
- **BUT - significant toxicities, such as myelosuppression and peripheral neuropathy, limit the effectiveness of paclitaxel-based treatment regimens.**

Ideal for pre|CISION™ tumour activation to create safer and proprietary pro-drugs.

Conservatively assume the pre|CISION™ prodrug versions of these can achieve similar market sizes delivering 5-10% royalty to Avacta plus development milestones.

Potential for a pipeline of pre|CISION pro-drugs, some of which have already been synthesized, with an addressable market of many \$bn pa.

Including but not limited to:

- preCISION Velcade
- preCISION Paclitaxel
- preCISION Oxaliplatin
- preCISION Gemcitabine
- preCISION Capecitabine
- preCISION PARP inhibitor
- preCISION PD-1 Inhibitor
- preCISION AKT inhibitor
- preCISION Balixafortide

Partnered Programmes Update



- (2018) multi-target agreement to develop Affimer® therapeutics in several disease areas.
- (2020) partnership expanded to include Avacta's Affimer XT™ technology for serum-half life extension.
- (2021) LG has successfully carried out certain in vivo studies with a PD-L1/XT molecule and is taking that asset into pre-clinical development which has triggered an undisclosed milestone payment to Avacta.



- (2019) collaboration and option agreement to develop Affimer-drug conjugates combining Affimer® technology with (PBD)-based warhead and linker technologies (licensed by ADCT from AstraZeneca).
- Avacta has delivered Affimer binders to a target nominated by ADCT.
- ADCT has carried out an evaluation and is not taking its option to develop the Affimers further.



- (2021) a license for Avacta's pre|CISION technology for the development of tumour-activated radiopharmaceuticals.
- Potential to improve targeting the radioligand treatment to cancer cells.
- First research programme initiated by POINT.



- (2020) JV (AffyXell) developing next generation cell and gene therapies incorporating Affimer proteins.
- (2021) AffyXell Series A funding of \$7.3m to achieve key pre-clinical milestones.
- Affimer molecules generated against first two targets.
- Good progress with in-vitro and in-vivo studies of lead Affimer molecules and engineered MSCs.

Scientific Advisory Board

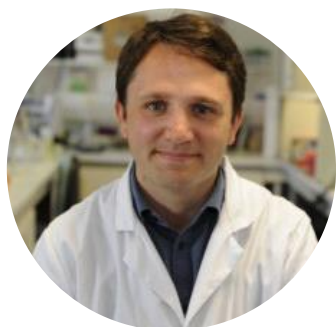


Professor James Spicer MB., BA., PhD., FRCP is Professor of Experimental Cancer Medicine in the School of Cancer & Pharmaceutical Studies at King's College London, and Consultant in Medical Oncology at Guy's & St. Thomas' Hospitals. He has a PhD in cancer biology, and a degree in biochemistry from the University of Oxford. He has established and runs a world-leading Phase 1 clinical trials programme in solid tumour oncology at Guy's Hospital, where the portfolio of studies includes novel immunotherapies discovered and developed at King's as well as many externally sponsored studies.



Professor Krishna Komanduri, M.D. is Chief of the Division of Transplantation and Cellular Therapy at the Sylvester Comprehensive Cancer Center at the University of Miami, holds the Kalish Family Chair in Stem Cell Transplantation and serves as the Associate Chief Medical Officer for Clinical Innovation at Sylvester. He is a Professor of Medicine, Microbiology and Immunology and a physician-scientist with a laboratory focused on T cell immunology in cancer. Dr. Komanduri serves on the United Health Care Oncology Advisory Committee and on the Optum Health Blood and Marrow Transplantation Advisory Committee. He is a past Chair of the American Society of Hematology Scientific Committee on Host Defense, is the current Chair of the ASTCT Cellular Therapy Committee and Chair-Elect of the Government Relations Committee.

Among his honors, he was elected into the American Society for Clinical Investigation (2009), and was recently inducted into the Henry Kunkel Society (2021) and into the second class to be named Fellow of the American Society for Transplantation and Cellular Therapy (2021).



Dr Stéphane Champiat MD, PhD is a physician at Gustave Roussy Cancer Center in Villejuif, France. He has been working since 2012 in the Drug Development Department of Gustave Roussy where he is involved in the development of cancer therapeutics, in particular new immunotherapies. He has been principal investigator or co-investigator of more than 50 phase I clinical trials run by many of the world's leading pharmaceutical and biotech companies. He is particularly involved in the coordination of the immunotherapy toxicity management program and the development of the intra-tumoral immunotherapy strategy at Gustave Roussy.



Powerful Diagnostics

AffiDX® SARS-CoV-2 Antigen Rapid Test

Affimer®
pre | CISION™



AffiDX® SARS-CoV-2 Antigen Lateral Flow Test



Accurate detection, comfortable sample collection,
and interpretation of results in just 20 minutes.



The AffiDX® SARS-CoV-2 Antigen Lateral Flow Test is an ideal solution for point-of-care and decentralised testing to identify individuals with higher viral loads of SARS-CoV-2 that increase the likelihood of transmitting the infection to others. Wholly developed and manufactured in the UK utilising accurate, flexible Affimer® technology, and validated against emerging variants of SARS-CoV-2.

AffiDX® SARS-CoV-2 Antigen Rapid Test

Features and Benefits

- ✓ **Patient-Friendly**
Anterior nares (nasal) swab samples for more comfortable collection
- ✓ **Reliable Results**
Accurate for identifying individuals likely to be infectious: **98% sensitivity** and **99% specificity**
- ✓ **Validated Against Delta Variant**
Routine monitoring of all emerging variants to ensure continued diagnostic accuracy
- ✓ **U.K Made**
Developed and manufactured in the United Kingdom
- ✓ **Accessible**
Suitable for Point of Care settings and allows for decentralised testing
- ✓ **Environmentally-Friendly Packaging**
Cardboard kit box can be recycled after use
- ✓ **Convenient**
Contains everything needed to run a test with no additional equipment required
- ✓ **Practical**
Room temperature storage, transportation and testing

<https://avacta.com/diagnostics/products/validation-of-affidx-sars-cov-2-antigen-lft-with-variants-of-concern/>

AffiDX[®] SARS-CoV-2 Antigen Rapid Test

Clinical Performance

Affimer[®]
pre | CISION[™]

Clinical Sensitivity (Ct < 31) 98.0%; Clinical Specificity 99%

PCR ¹ Result (Ct Range)	Number of Samples Tested in Ct Range	Avacta [®] AffiDX [®]		Clinical Sensitivity by Ct Range ¹		
		Positive	Negative	Cumulative Ct Range	% Cumulative Sensitivity	95% CI
< 27	52	52	0	0 - 27	100.0 %	(93.1 - 100.0 %)
27 - 28	7	6	1	0 - 28	98.3 %	(91.0 - 99.7 %)
28 - 29	18	18	0	0 - 29	98.7 %	(93.0 - 99.8 %)
29 - 30	19	19	0	0 - 30	99.0 %	(94.3 - 99.8 %)
> 30	2	1	1	All	98.0 %	(92.9 - 99.4 %)
TOTAL	98	96	2		98.0 %	(92.9 - 99.4 %)

PCR Result	Number of Negative Samples Tested	Avacta [®] AffiDX [®]		Clinical Specificity ²	
		Positive	Negative	% Specificity	95% CI
Negative	102	1	101	99.0 %	(94.7 - 99.8 %)

1. Applied Biosystems TaqPath COVID-19 CE-IVD RT-PCR Kit

2. Additional clinical data obtained since CE mark (236 negative samples): specificity 99.6%

Growing commercial traction for AffiDX professional-use antigen test and significant progress towards self-test approval

- Current manufacturing capacity at GAD now c.1 million tests per month.
- Manufacturing process has been transferred to Abingdon Health and the validation batches are now entering production.
- Abingdon Health could add a further 1-2 million tests per month capacity.
- Manufacturing partners in Europe and Asia with further significant capacity under evaluation.
- AffiDX professional-use antigen test:
 - Direct sales focusing on large supply contracts with corporates, elite sports, travel and testing services in UK and Europe;
 - Distributors: Calibre Scientific in UK, EU;
 - Regulatory approvals and distributors being established in APAC and other overseas markets.
- Excellent progress being made towards self-test regulatory approval with Medusa19 with the submission of the regulatory documentation to a notified body in Europe.

APAC region
accounted for 37%
of SC2 antigen test
sales in 2020

First ever Affimer® IVD product brought to market and first-in-human phase I study of first preCISION pro-drug initiated

- **Diagnostics**
 - There will be an ongoing global need for sensitive and reliable COVID-19 testing for many years.
 - AffiDX SARS-CoV-2 antigen flow test with market leading performance CE marked for professional use.
 - UK manufacturing capacity 2-3 million per month scalable in UK and abroad.
 - Commercial traction building through direct sales and distributors in UK, EU and overseas in key markets such as APAC region.
- **Therapeutics**
 - AVA6000 pro-doxorubicin: FPI August 2021 in Phase I first-in-human, open-label, dose-escalation and expansion study in patients with locally advanced or metastatic selected solid tumours.
 - Aiming for IND filing before the end of 2021 for Phase I study for AVA6000 in US.
 - Pre-clinical development milestone achieved in LG Chem programme triggering an undisclosed milestone payment.
 - AffyXell Series A funding of \$7.3m and good progress with in-vitro and in-vivo studies of lead Affimer molecules and engineered MSCs.
 - Multiple development candidate selection milestones across all programmes during next 12 months.
- **Strong balance sheet to support core businesses and working capital for COVID testing opportunity**



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