



Avacta Group plc

June 21, 2021

Affimer[®]
pre|CISION[™]
AffID[®]DX[®]

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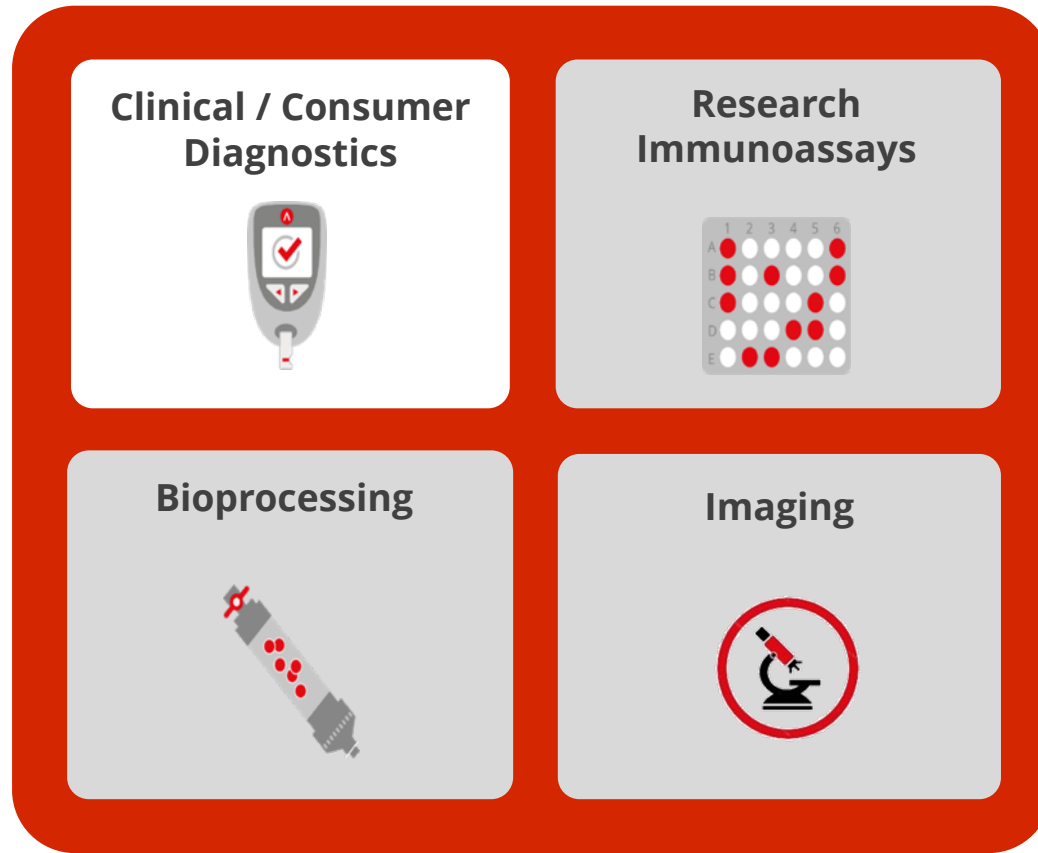


Diagnostics Division

Significant commercial opportunity for market leading SARS-CoV-2 antigen test with growing pipeline of in-house IVDs to drive longer term revenue

Affimer® Reagents Strategy

Broad life sciences market opportunities; clear in-house focus on diagnostics



Astrea
Bioseparations

Avacta's Diagnostics Focus

In-house and partnered pipeline of diagnostic tests for licensing

Key Benefits of Affimer® Diagnostics

- Highly specific diagnostic reagents
- Security of supply
- Success with difficult targets
- Robust and stable
- Flexible formatting
- Low cost of manufacture
- Freedom to operate around antibody IPR

AffID[®]

In-house and Partnered Pipeline

- In-house development pipeline priorities:
 - SARS-CoV-2 antigen: COVID-19
 - Cortisol: stress
 - TRAIL, CRP: sepsis
 - VitB12: anemia
- Pipeline of technology evaluations aimed at licensing deals mainly in the diagnostic market.
 - Biokit, part of the Werfen Group, licensed certain Affimer reagents for diagnostic product development in February 2021.
 - Astrea Bioseparations licensed the platform (£0.5m upfront) for affinity purification in December 2020.

COVID-19 Rapid Testing Market Dynamics

A complex, competitive market with a large number of antigen tests available of varying performance and price

- Diverse legislation/healthcare policies:
 - General population settings: workplaces, travel, events.
 - Outbreak investigation / contact tracing for confirmed cases.
 - Widespread community transmission / isolation of positive cases.
 - Monitoring trends in disease incidence in specific communities.
- Normally distinct markets for professional-use and self-test IVDs are overlapping but the regulatory/legal distinction remains in place.
- Test performance is highly variable – adoption driven by supply rather than quality.
- End user price has been driven down by cheap tests – €3-4 – so margins are tight for manufacturers and distributors.
- Demand remains high and is expected to do so for 3-5 years.
- Specimen collection & processing requirements are important differentiators.
- European or UK origin is an important differentiator.
- Performance will drive sales in longer term.

AffiDX® SARS-CoV-2 Antigen Rapid Test

A 20 minutes rapid antigen test using anterior nasal sampling

INTENDED USE: The Avacta® AffiDX® SARS-CoV-2 antigen lateral flow test is a qualitative *in vitro* diagnostic (IVD) test to detect SARS-CoV-2 antigen in human anterior nasal swab samples. The test is to be used to identify individuals with higher viral loads of SARS-CoV-2 that increase the likelihood of transmitting the infection to others. The test is intended for professional use only.

Key Benefits

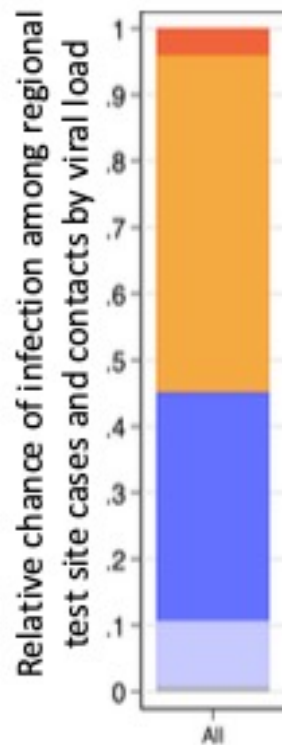
- Patient-friendly nasal sample collection
- UK developed and UK manufactured
- High quality with excellent clinical performance
- Rapid and simple
- Monitored against emerging variants



What does “infectious” mean?

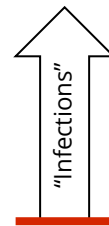
PCR Ct value < 27 suggested as a measure of an “infectious” viral load

- Ct = Ct Value = the number of amplification cycles needed for a virus to be detected by PCR; the lower the Ct, the higher the viral load in the sample



Data taken from Liverpool COVID-SMART Pilot, Dec 2020.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950695/s0958-liverpool-covid-smart-evaluation.pdf

	Viral load RNA copies/ml	Approximate Ct	
		Porton	Glasgow
	>100M	<14.9	<12.2
	1-100M	14.9-21.5	12.2-18.3
	10K-1M	21.5-28.1	18.3-24.4
	100-10K	28.1-34.6	24.4-30.5
	<100	>34.6	>30.5



AffiDX® SARS-CoV-2 Antigen Rapid Test

Market leading clinical performance showcasing the power of the Affimer® platform

- Clinical performance was determined by testing a total of 200 samples (98 pos., 102 neg., as determined by RT-qPCR) at a clinical study conducted in the EU.
- Clinical sensitivity (Ct ≤ 27): **100.0%**
- Clinical sensitivity (Ct < 31): **98.0%**
- Clinical specificity: **99.0%**
- Analytical Limit of Detection (LoD): 6×10^2 pfu/mL
- No cross reactivity of Affimer® reagent with MERS-CoV S1, HCoV-229E S1, HCoV-HKU1 S1, HCoV-NL63 S1 or HCoV-OC43 S1
- Variants of Concern verified:
 - UK-Kent (B.1.1.7): validated
 - South Africa (B.1.351): validated
 - Brazil (B.1.1.28): partial validation complete - full validation pending availability of virus from PHE
 - India (B.1.617.2): awaiting availability of virus from PHE
- Affimer® flexibility to rapidly adapt to new variants or new emergent strains ... or the next pandemic

AffiDX® SARS-CoV-2 Commercialisation

CE mark and product registration for UK and EU for professional use

- CE mark and product registration in EU and UK received.
- Global Access Diagnostics Ltd (GAD) manufacturing commercial product.
- Abingdon Health plc (LON: ABDX) establishing manufacturing processes equivalent to GAD's.
- BBI Solutions could not deliver in terms of time/cost of goods (COGs).
- Ongoing negotiations with other UK, EU and overseas manufacturers to achieve volume and required COGs.
- Combined UK manufacturing capacity when fully scaled-up that is available to Avacta (depending on access to equipment funded by HM Government) is 5 – 30 million tests per month from Q3.
- Additional overseas capacity can provide up to 1 million tests per day with short (6-8 weeks) technology transfer time and lower COGs.

AffiDX[®] SARS-CoV-2 Commercialisation

Direct sales and distribution partners form Avacta's routes to market

- Multiple commercial negotiations with distributors and end users ongoing in EU and UK for professional use test.
- Avacta direct sales activity is targeting:
 - large corporates for workforce testing;
 - work-force testing service providers;
 - travel related businesses (airlines, airports);
 - events companies;
 - care homes and other social and healthcare businesses required to test their employees.
- First distribution partnership now in place with Calibre Scientific:
 - Non-exclusive distribution agreement serving EU and UK.
- Avacta remains engaged with the UK government procurement pathway through Porton Down¹.
- Other overseas non-EU customers/distributors in discussion.

1. <https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/protocol-for-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices>

Therapeutics Division

Transformation in the near term into a clinical stage biotech with a strong pipeline of next generation cancer therapies based on two proprietary platforms

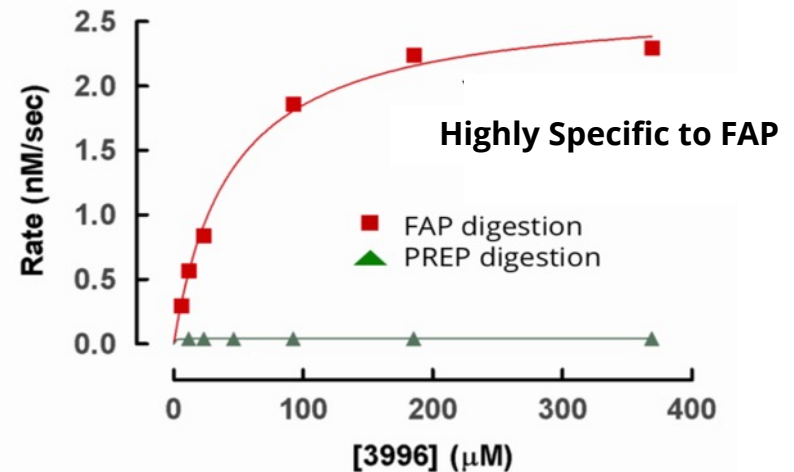
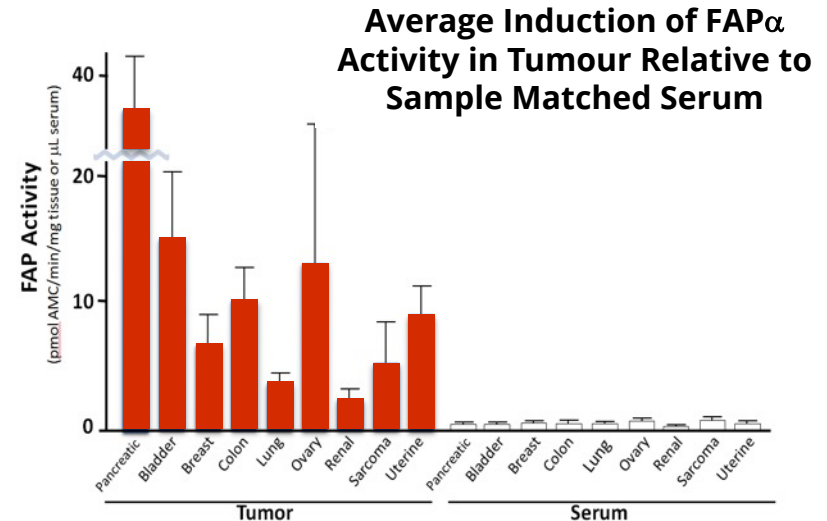
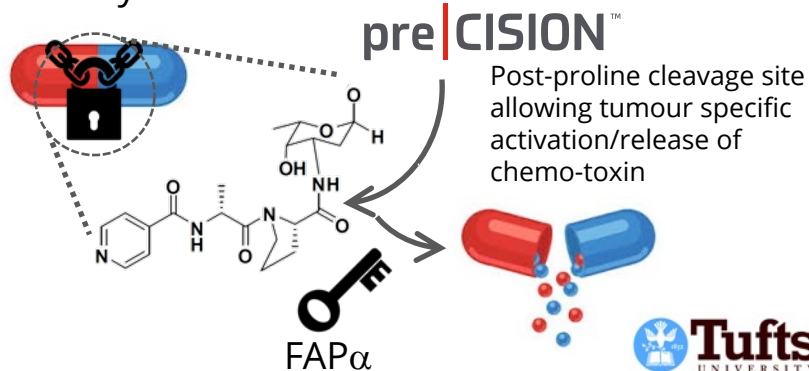


The pre|CISION™ Platform

Tumour Targeted Activation of Cancer Therapies

Affimer®
pre|CISION™

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



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

Background

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

Treatment is limited to six cycles (60-75 mg/m² every 3 weeks) due to cumulative cardio-toxicity (450mg/m²).

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

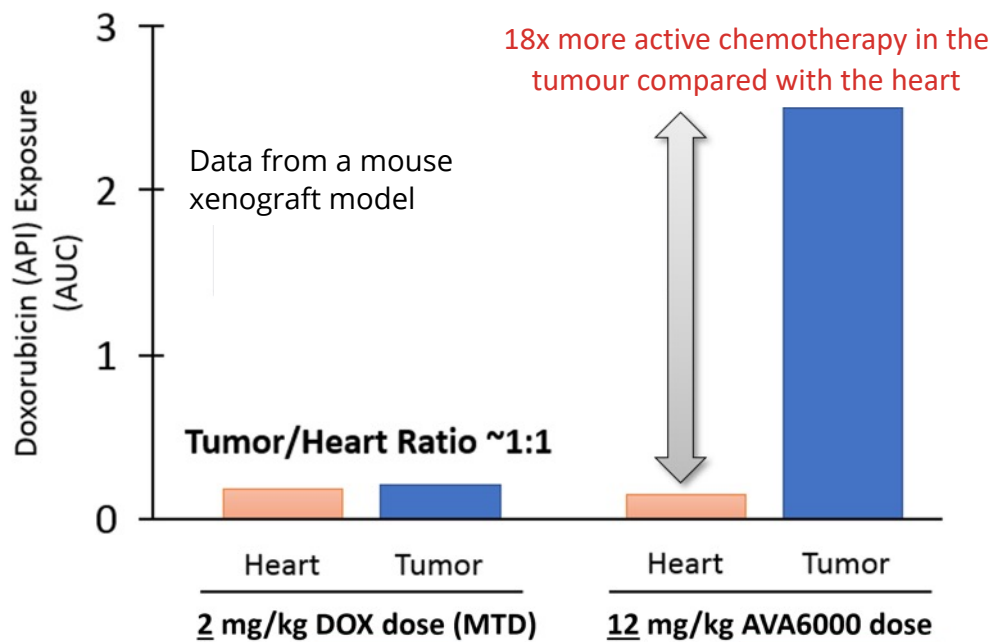
Improved safety could permit many more cycles of treatment per patient at the same dosing level.

AVA6000 Market Opportunity

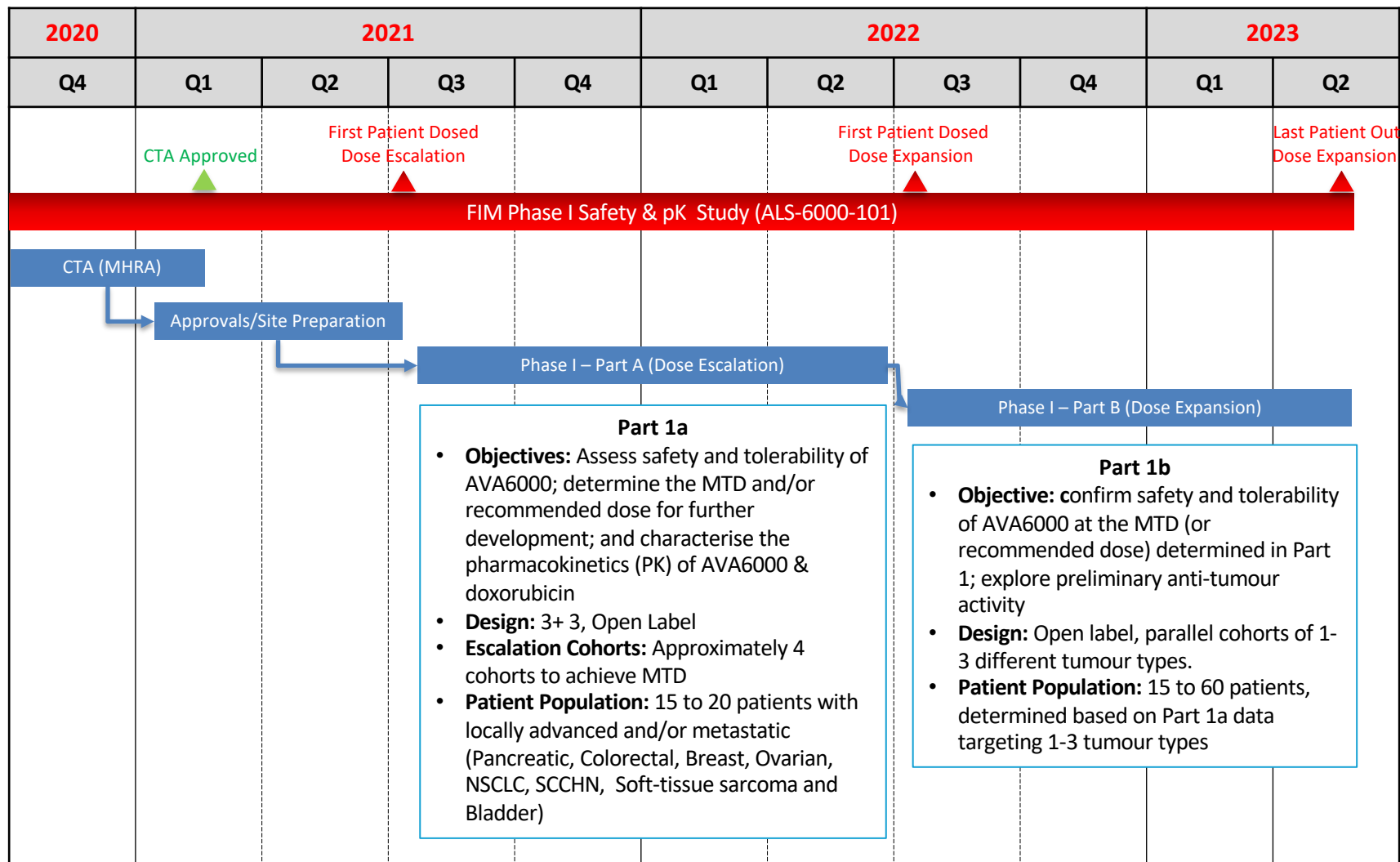
For three indications only (ASTS, breast and ovarian cancer) peak sales for a safer/more efficacious form of dox in the US/EU alone is estimated to be **\$1.5bn* pa with a 5-10% royalty to Avacta plus development milestones in near term.**

* Commercial Evaluation: AVA6000 (Globe Life Sciences, March 2020)

Targeting of Drug to Tumour Spares Heart Tissue

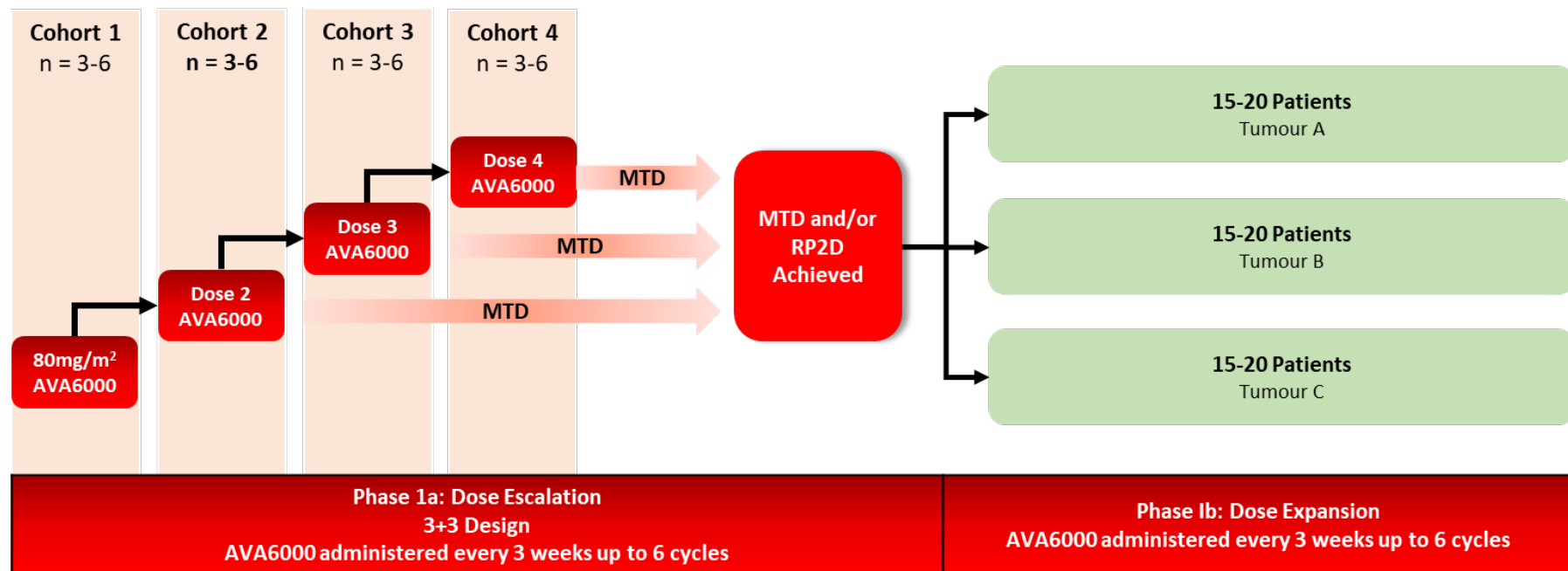


AVA6000 Phase I Study Timeline



MTD - Maximum Tolerated Dose

AVA6000 Phase I Study Design



- Starting dose for Cohort 1 of 80mg/m² AVA6000 (administered every 3 weeks)
- Subsequent AVA6000 Doses guided by safety data & PK data
- 15- 20 patients in dose-escalation phase; 15-60 patients in dose expansion phase
- Locally advanced (unresectable) or metastatic solid tumours
 - Dose Escalation: Pancreatic, Colorectal, Breast, Ovarian, NSCLC, SCCHN, Soft-tissue sarcoma and bladder
 - Dose Expansion: Select 1-3 tumour types based on data from Phase 1a

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-proteasome inhibitor

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:

- Pre|CISION pro-proteasome inhibitor
- Pre|CISION Paclitaxel
- Pre|CISION Oxaliplatin
- Pre|CISION Gemcitabine
- Pre|CISION Capecitabine
- Pre|CISION PARP inhibitor
- Pre|CISION PD-1 Inhibitor
- Pre|CISION AKT inhibitor
- Pre|CISION Balixafortide

Major value inflection points in the near term across the Group

- **Diagnostics: substantial opportunity for AffiDX[®] rapid antigen test**
 - Multiple commercial deals with distributors and end users expected in H2.
 - Demand for rapid COVID-19 testing expected to remain high for years.
 - Strong pipeline of non-COVID diagnostic tests in development.
- **Therapeutics: driving significant long term value**
 - AVA6000 pro-doxorubicin: expecting to dose first patient in late July.
 - Initial pharmacokinetic data expected before the end of 2021.
 - IND filing for AVA6000 expected in Q4.
 - Multiple Affimer and pre|CISION 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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