

Amplia Therapeutics Limited Bioshares Presentation - July 2019

ASX:ATX



Amplifying Immuno-oncology

Notice

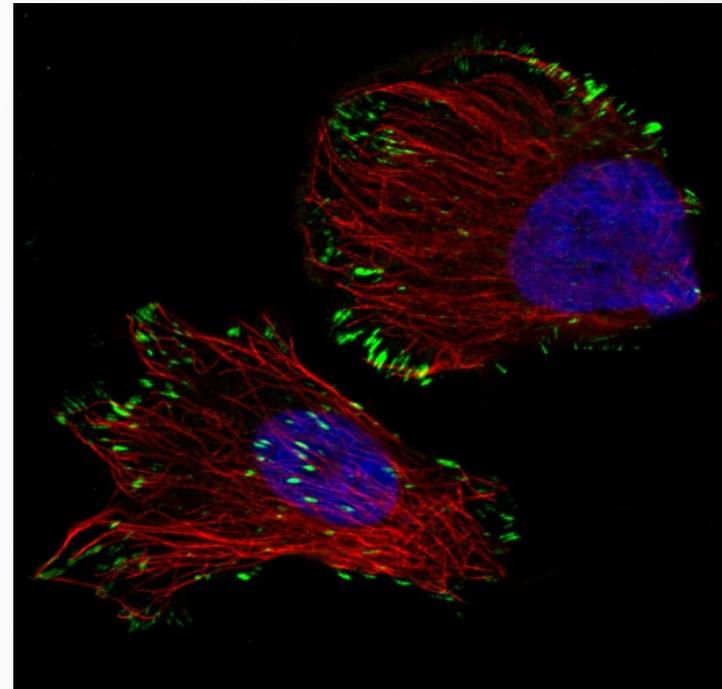
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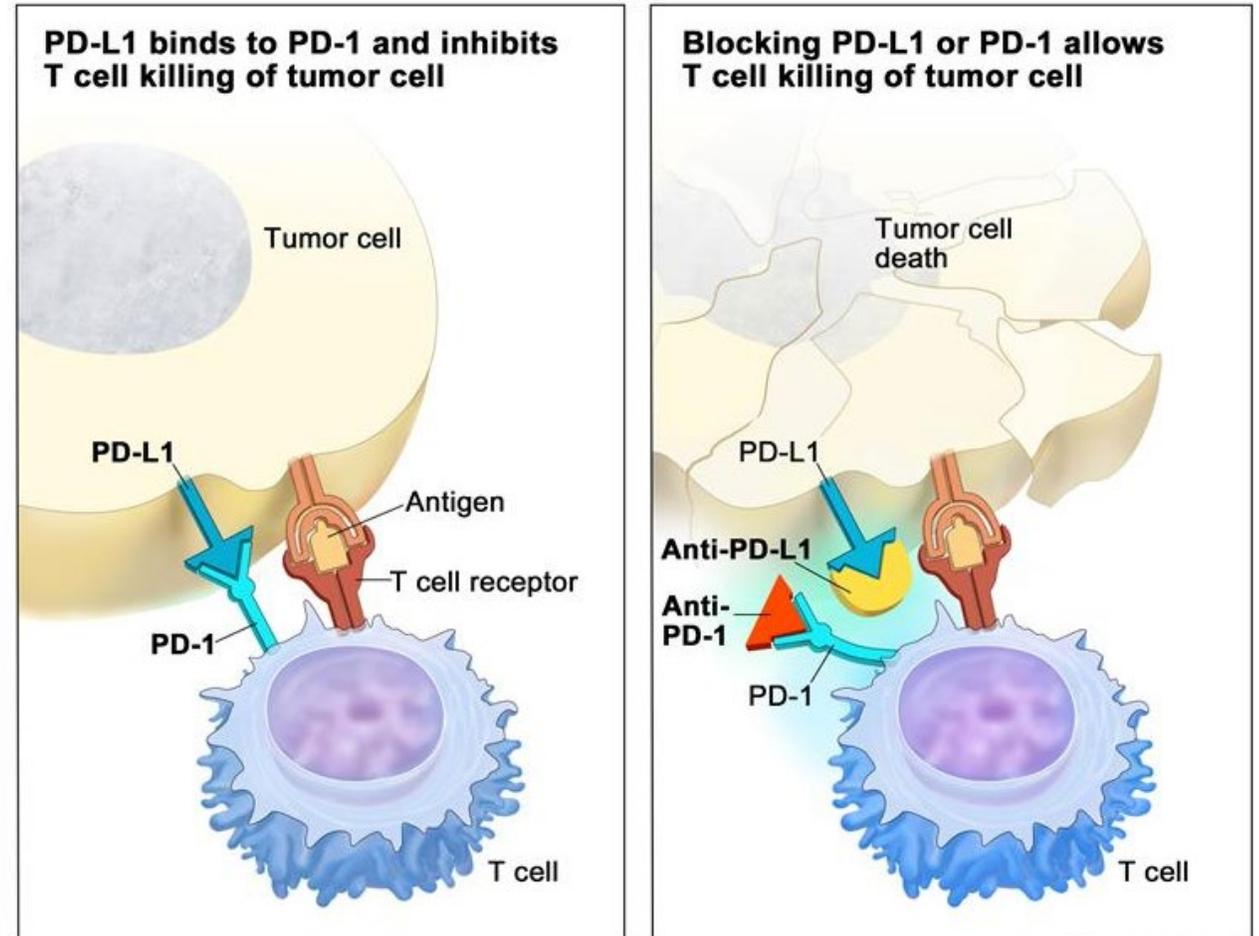
Amplia Therapeutics

- A pharmaceutical company advancing a pipeline of Focal Adhesion Kinase (FAK) inhibitors offering therapeutic potential in cancer and fibrosis
- Current focus is on highly selective FAK inhibitors
 - Combinations with immuno-oncology products
 - Wide range of fibrotic diseases



Checkpoint Inhibitor Primer

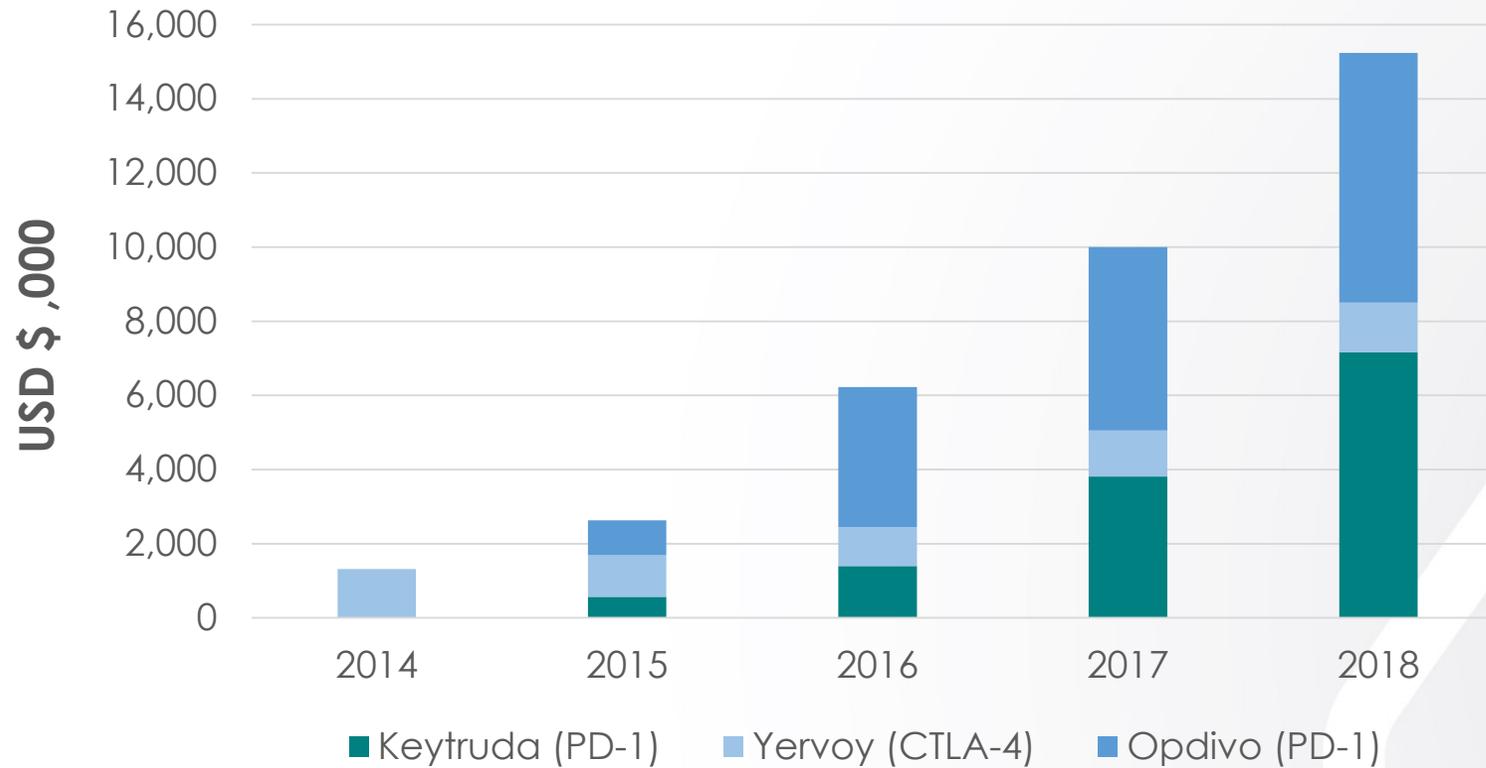
- Many cancers evade detection by the immune system by co-opting negative regulators of the anti-tumour immune response
- One such immunosuppressive action is achieved by tumour upregulation of checkpoint proteins such as PD-L1
- Interaction of PD-L1 with PD-1 blunts the response of cytotoxic lymphocytes
 - PD-L1 and PD-1 are then referred to as 'checkpoint proteins'
- Antibodies directed at checkpoint proteins block the PD-L1/PD-1 interaction and restore the anti-tumour immune response



Reproduced from [National Cancer Institute](https://www.nationalcancerinstitute.gov)

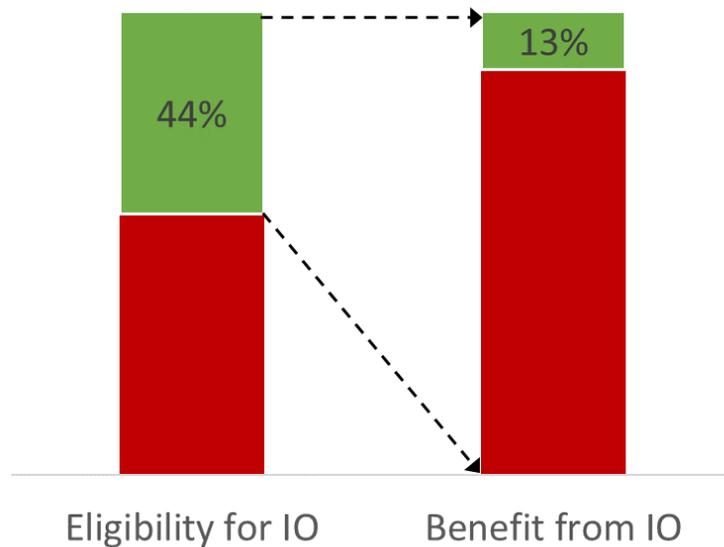
Checkpoint Inhibitor Market Growth

Annual Sales of Market Leading Checkpoint Inhibitors



The Need

Eligibility for Immunotherapies in Cancer and Their Benefit to Patients

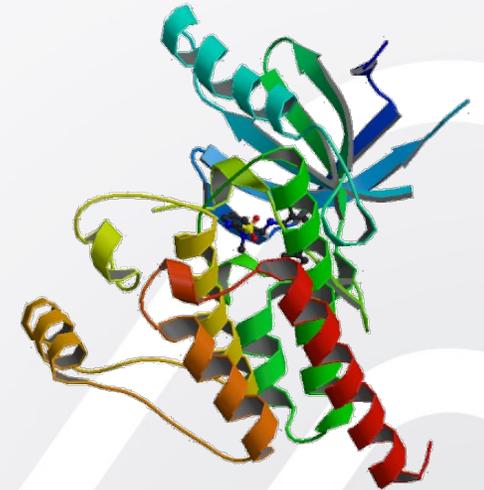


Adapted from
Haslam A, Prasad, V., *JAMA Network Open*. 2019;2(5):e192535

- Although checkpoint inhibitor drugs have revolutionised cancer treatment, complete response rates to these agents are still low
- Only 44% of all cancer patients are eligible to receive these drugs and, of these, only 13% respond completely to therapy
- Why do ~87% of eligible patients not yet fully respond to checkpoint inhibitors?
 - Certain tumours are 'cold' and remain invisible to the immune system
 - Checkpoint blockade is not sufficient to overcome the immunosuppressive tumour microenvironment
- Combination therapies are a key frontier

Focal Adhesion Kinase – a ‘Bad Actor’ in Cancer

- FAK is upregulated in many cancers and plays multiple roles
 - Involved in cellular adhesion and migration
 - Promotes cancer cell survival and proliferation
 - Contributes to the establishment of an immunosuppressive tumour microenvironment
 - Regulation of immunosuppressive chemokines and cytokines
 - Suppression of the antitumour CD8+ T-cell response
 - Promotes fibrosis, altering the tumour’s physical environment
- FAK ‘buffers’ tumour cells from stress
 - Current theory is that certain tumour types become ‘FAK dependent’



Crystal Structure of FAK

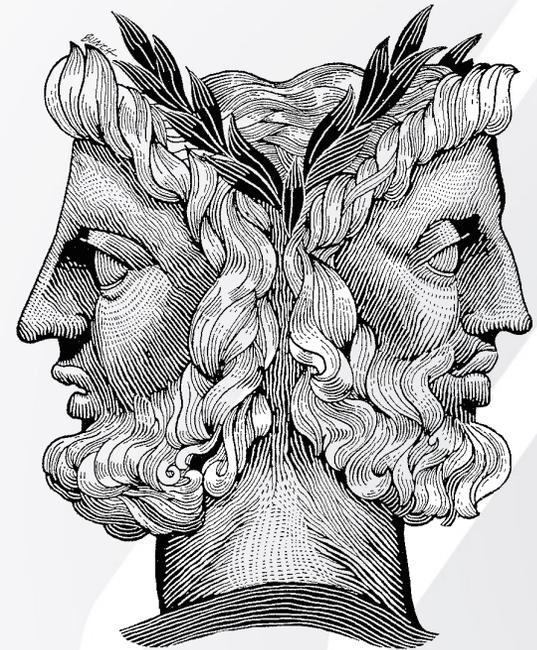
Amplia’s premise

FAK inhibitors will improve the efficacy of front-line cancer immunotherapies by suppressing the tumour-protective properties of FAK

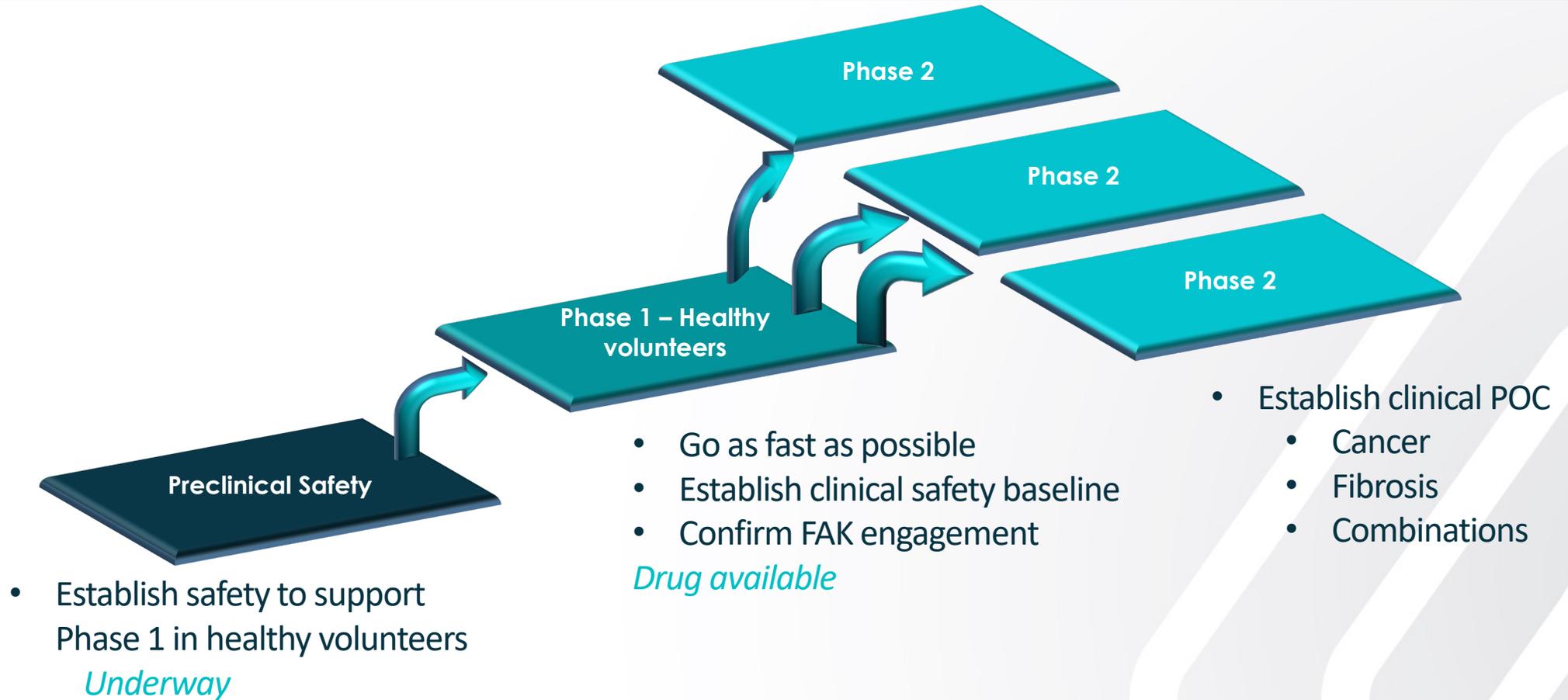
Amplia's Therapeutic Focus

- Dual anti-fibrotic and immunomodulatory action of FAK inhibitors may be advantageous in fibrotic cancer
 - Growing case for potential of 'mechanotherapeutics' (including FAK inhibitors) in fibrotic cancers*
- Fibrotic cancers including pancreatic and ovarian cancer
 - Pancreatic cancer has the worst survival outcome of the 21 most common cancers
 - Ovarian cancer ranks fifth in cancer deaths among women

* [Pancreatic cancer provides testbed for first mechanotherapeutics. *Nature Biotechnology*, 12th July 2019](#)



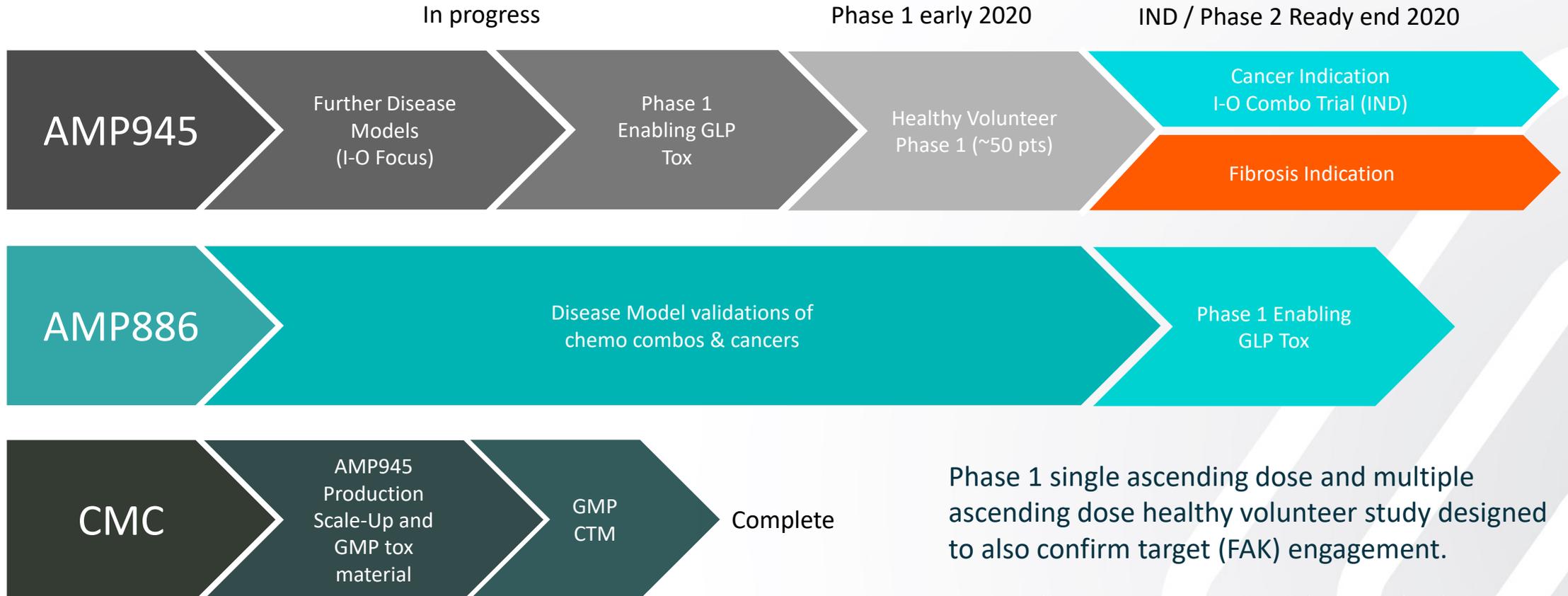
Amplia's Early Clinical Development Strategy



Amplia's Early Clinical Development Strategy

- Perform first-in-human studies in healthy volunteers to establish a safety baseline
 - Assess safety, tolerability
 - Confirm engagement of FAK
- Use established safety profile as a foundation for multiple combination opportunities
- Advantages:
 - 'Clean' safety data without confounding effects of disease symptoms;
 - Shorter, more predictable costs and timelines;
 - Consistent with recommendations of [SITC Combination Therapies Taskforce](#).

High-level Development Plan (18 months)



Phase 1 single ascending dose and multiple ascending dose healthy volunteer study designed to also confirm target (FAK) engagement.

Data will support Phase 2 trials in multiple combinations/therapeutic areas.

Competitive Landscape

Agent	Company	Status	Notes
VS-4718 (PND-1186)	Verastem	P1 (various studies)	First generation candidate
BI-853520	Boehringer-Ingelheim	P1 (NCT01335269) & (NCT01905111)	Two trials completed (Aug 14 & Dec 15)
CT-707	Centaurus Pharma	P1 (NCT02695550)	Unknown status. Last update Mar 17. Single site China. Questions about selectivity
GSK-2256098	GSK	P2 (NCT02428270)	Combo with chemo (Trametinib) in pancreatic cancer (n=16). Target completion Dec 19
VS-6063 (PF-04554878)	Verastem	3 x P2 (monotherapy)	1 terminated, 1 completed Apr 17 (?) not reported, 1 recruiting target completion Sep 19
VS-6063	Verastem	P1/2 (NCT02758587)	Combo with Pembrolizumab in several cancers (Target n=59). Target completion Dec 21
VS-6063	Verastem	P1/2 (NCT03287271)	Combo with SOC chemo in ovarian cancer (Target n=90). Target completion Oct 24
VS-6063	Verastem	P2 (NCT03727880)	Combo with Pembrolizumab in pancreatic cancer (Target n=36). Target completion Feb 23

- Established target but little commercial congestion due to lack of highly selective FAK inhibitors
- Clinical development now focused on combo therapy in oncology setting
- Verastem (NASDAQ: VSTM, Market Cap USD \$120m) nearest comparator however our molecules are highly differentiated, both in their selectivity and multi-action effect

Differentiation of Amplia FAK Assets

- Excellent potency, selectivity and pharmacokinetics
 - AMP945 is a highly selective FAK inhibitor
 - AMP886 is a multi-action molecule that hits two other important cancer pathways – VEGFR3 and FLT3
- Strong intellectual property position
 - Issued patents in all commercially important jurisdictions (exp. 2033/34)
 - Optimised formulation application filed March 2019 with potential to extend IP protection out to 2040

Near Term Catalysts - Summary

- Amplia's strategy is to position its assets to maximize opportunities for combination efficacy studies in cancer
 - Fibrosis indications further underpin value
- Multiple near- and mid-term value inflection points
 - Phase 1 trial in healthy volunteers in 2020
 - IND opening Q3 2020
 - Phase 2 ready late 2020
 - Ongoing partner engagement and opportunities to combine with approved products
- Amplia's experienced drug development team is strongly positioned to optimise asset value



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