Innate Immunotherapeutics

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Innate Immunotherapeutics proposed acquisition of Amplia Therapeutics – Questions & Answers

Innate Immunotherapeutics Limited (ASX Code: IIL) announced on 23 March 2018 that it had entered into a conditional agreement with the shareholders of Amplia Therapeutics Pty Ltd (Amplia) to acquire all of the shares of Amplia in consideration for the issue of Innate ordinary shares. In acquiring Amplia, Innate will acquire that company's Focal Adhesion Kinase (FAK) cancer programme.

The following questions and answers provide additional information about this transaction:

1. What is Focal Adhesion Kinase (FAK) and why does it have potential in cancer treatment?

FAK has emerged as a high-potential target in cancer for two reasons. Firstly, it has the ability to control the tumour immunity environment, including fundamental regulatory functions that contribute to the way that cancer cells hide from the immune system.[1] Secondly, FAK has a synergistic effect with a number of other important targets in cancer such as mTOR, SRC and BRAF,[2] for which there are drug combinations that could be "boosted" through combined use with a FAK inhibitor.

2. Is FAK a potential target in other indications?

In addition to its role in cancer, FAK is also implicated in fibrosis,[3] which opens the door to it being targeted in several chronic disease applications. Fibrosis is a major drug development focus area and our early clinical development plan enables the collection of data on the FAK assets in a manner that will enable both the cancer and fibrosis potential to be evaluated early.

3. What stage of development are the Amplia FAK inhibitor drug candidates?

The FAK drug candidates are in pre-clinical development, however there is a considerable body of data from the pre-clinical cancer models run to date that points to efficacy. In addition there is a detailed manufacturing package demonstrating that industrialising drug production appears viable. Overall the FAK drug candidates that will be acquired through the Amplia transaction appear to be highly attractive compounds for clinical development possessing excellent potency and drug-like properties, biological selectivity, bioavailability, and manufacturing scale-up potential.

[1] *Cell*, Volume 163, Issue 1, 24 September 2015, p160-173
[2] *Cancer Cell*, Volume 27, Issue 4, April 2015, p429–431, 13
[3] *Nature Scientific Reports*, Volume 6, 2016, Article number: 19276

4. Are other pharmaceutical companies are actively researching FAK?

Yes, there are competing programs in a modest number of medium- and large- pharma companies. FAK is generally recognized by immuno-oncology KOLs as a potentially important target, as evidenced by certain collaborations such as the Verastem (NASDAQ: VSTM) - Pfizer alliance. Relative to these programs, the FAK assets in Amplia's hands appear superior in terms of biological properties and target selectivity. Should the synergies between FAK and immuno-oncology drugs such as checkpoint inhibitors be demonstrated clinically, we believe FAK assets will be in significant demand by leading cancer immunology firms.

5. What are the possible advantages of the Amplia FAK inhibitors?

The Amplia FAK inhibitors appear to have superior biological properties compared to competing molecules in terms of drug-like properties, biological selectivity, and manufacturability. The AMP945 drug candidate is a highly selective inhibitor of FAK with a very clean off-target profile, meaning that the drug is expected to be well tolerated in humans. In contrast, the AMP886 drug candidate has a multi-action drug profile with FLT and VEGFR3 also inhibited by the molecule. (FLT and VEGFR3 are also important regulatory targets in cancer). We believe these advantages will enable us to deploy a FAK-targeted asset into distinct – and differentiated – cancer applications based on these superior properties.

6. What is the patent life of the Amplia assets?

Composition of matter and method to treat (proliferative diseases such as cancer) patents have been granted or are in national phases in major markets. The patent life of the assets extends (without any calculation for patent term extensions) until 2033. There are also several development activities in progress which we believe will broaden and/or extend the current intellectual property position.

7. What are license terms of the Amplia assets?

Amplia has been granted an exclusive worldwide licence to commercialise the assets. The license agreement with Cancer Research UK (CRUK) is an industry standard, competitively structured agreement for assets at this stage of development. There are modest milestone payments due as a function of clinical development milestones, repayment of historical patent costs as well as low-medium single digit royalties on sales (including discounted royalties for selling as part of a combination therapy). Over the next two years, we expect that the financial impact of obligations under the license agreement are unlikely to exceed $200,000.

8. What was the basis for the transaction valuation?

The post transaction ownership of Innate, being 55% existing IIL shareholders and 45% new ex Amplia shareholders was arrived at after taking into account the relative values of the two companies tangible and intangible assets as viewed by the directors. These assets included the respective drug candidates (MIS416, AMP945 and AMP886), cash, drug development experience, and relevant high quality collaborative networks.

9. What scientific and IP diligence was completed on the assets?

Innate Director Dr Robert Peach led the review of the literature relating to FAK and the substantial body of preclinical data relating to Amplia's specific FAK inhibitors. In Dr Peach's opinion the team at the Melbourne based Cancer Therapeutics Cooperative Research Centre (CTx) had done an excellent job selecting and characterizing AMP886 and AMP945 before licensing them to Cancer Research Technology Limited (CRUK) and then Amplia. The IP trail was carefully reviewed in detail by both Innate and an experienced outside IP/licensing attorney. This included a review of the evidence that 3rd party commercial and academic collaborations preserved the exclusivity and freedom-to-operate of the assets.

10. What are the escrow arrangements for the incoming ex Amplia shareholders?

All Amplia shareholders, including CRUK and CTx, have agreed to a voluntary escrow of 2 years.

11. Who will be the CEO and management team after the transaction?

To date, the Innate and Amplia team have demonstrated a very solid working relationship. Simon Wilkinson will remain the CEO of the group. He will take the leading role in both articulating the value proposition of Innate's new business focus as well as driving the translation of that proposition into tangible results. He will be supported by Mark Devlin, who will take the role of Chief Scientific Adviser. The other directors are all highly experienced in relative fields and will provide significant support to the management team in their role as non-executive directors.

12. When will Innate need to raise capital?

We believe that the current balance sheet will support pre-clinical activities for the Amplia assets, completion of various MIS416 related activities and working capital needs for approximately 12 months. We would expect to raise capital for a Phase I clinical program and ongoing operations in due course.

13. Has there been commercial / partnering interest in the assets?

Yes, all of the major immuno-oncology leaders are aware of Amplia's FAK assets and their potential. There are several collaboration opportunities that could evolve into commercial partnerships if the data was supportive. However, we would be unlikely to achieve a commercially meaningful partnering arrangement without initial human data.

14. When will the FAK assets be tested in humans and how?

The FAK assets are approximately 12 months away from being able to be tested in humans. Amplia already has an established manufacturing process to allow rapid progress through formal pharmacology studies and the move to initial clinical studies. In order to create a first-in-human data set that could enable commercial partnering discussions we currently plan to conduct a Phase I study in healthy volunteers under a CTN[4] in Australia. This is a very rapid and cost-effective way to obtain initial human experience and will produce a data set that, in

[4] https://www.tga.gov.au/clinical-trials

conjunction with appropriate further pre-clinical studies, will support a regulatory pathway to a Phase II trial in the US.

15. Will Innate conduct FAK R&D and clinical trials in Australia?

Yes, we expect that a significant proportion of our pre-clinical and clinically enabling R&D will be conducted in Australia and the initial clinical experience will likely be under the Australian CTN scheme. Such expenditures would be eligible for existing R&D tax incentives (noting that such incentives are subject to policy review from time to time).

16. What will happen to MIS416?

Data from an earlier preclinical programme in cancer combined with strong human safety data to date, suggests that MIS416 might have utility in one or more immuno-oncology (IO) applications. The in-licensing of the Amplia assets will firmly position Innate in the IO space and the combined team certainly has the relationships and industry connectivity to actively pursue related opportunities for MIS416.

17. Why are Innate's Directors recommending the Amplia transaction?

The combination of a very promising set of drug candidates that are relevant to Innate's drug development experience, relationships with leading international cancer research institutes, and a very strong injection of drug development and commercialization expertise, makes the Amplia transaction a compelling opportunity for Innate. The terms of purchase agreed with Amplia and CRUK are very much focused on the up-side, are preserving of financial resources, and are not excessively dilutive to existing Innate shareholders, given the current market capitalisation of the company.

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