WILSONS ADVISORY

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Company

Immutep Limited (IMM)

Breast Cancer + subq Keytruda thoughts

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Investment View

We maintain our OVERWEIGHT rating with a risked PT of $1.20/share for Immutep (IMM). IMM continues to impress with pipeline optionality and the potential of efti in earlier lines of treatment. With efti's safety profile and MOA there is strong rationale for immune priming in the neoadjuvant setting.

Announcement Highlights

- IMM announced a collaboration with George Washington University to run an investigator-initiated ph2 trial evaluating eftilagimod alpha (efti) as a neoadjuvant, being administered in combination with chemotherapy prior to surgery in patients with HR+/HER2- breast cancer. The study aims to enroll 50 patients with a primary endpoint evaluating pathological complete responses (pCR).

- Separately, Merck announced the approval of KEYTRUDA QLEX, a version of their blockbuster immune checkpoint inhibitor that can be administered subcutaneously in as little as 1 minute. This approval covers 38 indications, including 1L metastatic nonsquamous/squamous NSCLC, IMM's lead indication.

Wilsons' View

Initial analysis

The announcement of this IIT is the second of its kind, demonstrating both the desire for and the opportunity of efti to move into earlier lines of treatment and into the neoadjuvant setting. The study thesis is that efti's immune activation can potentiate anti-tumour immune responses that stem from exposure to chemotherapy, leading to high rates of pCR. In turn, improved pCRs can reduce tumour size, allowing for breast-conserving surgery and is associated with improved overall survival. AIPAC-003 (Phase II/III study in metastatic, HR+/HER2- disease) remains Immutep's focus for development in breast cancer and accounts for $0.22 (risked) and $0.80 (unrisked) of our valuation with peak sales of $1.1b. A successful trial could broaden the addressable market with ~18% of stage 2-3 HR+/HER2- patients receiving neoadjuvant chemotherapy[1].

Data from the first trial in the neoadjuvant setting EFTISARC-NEO a ph2 IIT in soft tissue sarcoma will be presented at the upcoming connective tissue oncology society on the 12-15 November 2025. These results provide some insight into the applicability of efti in the neoadjuvant setting although we currently point to the scientific rationale as a MHCII agonist. EFTISARC-NEO combined efti with radiotherapy and KEYTRUDA prior to surgery and met the primary endpoint of tumor hyalinization/fibrosis, a surrogate associated with improved overall survival.

Merck joins a developing field as the third approved subcutaneous PD-(L)1 inhibitor, following Roche's TECENTRIQ HYBREZA and BMS's OPDIVO QVANTIG. Merck highlighting KEYTRUDA QLEX with the fastest administration, as little as 1 minute, suggesting Merck will continue to maintain their lead in oncology. Merck is expecting to move ~30% of patients onto KEYTRUDA QLEX over the coming 18 months. The field is moving towards subcutaneous treatment to minimise the burden on healthcare providers. IV administered developing competition may be facing increased competition, Efti is administered subcutaneously as an adjunct, with a positive read to the direction of the field.

Earnings implications

No changes

[1] Liu, J., et al. (2025) Long-term survival outcomes of neoadjuvant chemotherapy in stage II-III HR+/HER2- breast cancer. Sci. Rep. 15(1) 30201

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