

Date

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Theme Alert Sector

Healthcare

Company Immutep Limited (IMM)

# Adding Autoimmune to the indication list

# | Announcement Highlights

Immutep have announced their plans for the first clinical study of their LAG-3 agonist, IMP761, for the potential treatment of autoimmune conditions. The trial will be a first-in-human safety Phase I trial to enroll ~49 healthy volunteers being conducted at the Centre for Human Drug Research (CHDR) in Leiden, Netherlands. The CHDR is an independent trials centre specializing in early stage and first-in-human drug research, with unique immunomodulatory challenge models that will help generate important pharmacological drug response data. To date, investors', including our own modelling, has been focused and limited to Immutep's immunooncology assets – namely Efti. IMP761 we have always seen as a compelling asset, albeit early in the pipeline. Moving this asset into clinical development this year (mid CY24 trial start) forces it to become a consideration in IMM valuation.

# | Wilsons' View

#### Initial analysis

Phase I IMP761 trial. The trial will seek to enrol 49 healthy volunteers to be administered IMP761 in a dose-ranging manner. Primary outcomes are focused on safety and tolerability as well as collection of Pharmacokinetic (PK) and Pharmacodynamic (PD) data. The trial will include a placebo group. The study will include use of CDHR's keyhole limpit haemocyanin (KLH) challenge model within the trial – a test designed in house to evaluate immunomodulatory response to investigational compounds (IMP761 in this case) that provides key clues as to potential immunomodulatory impacts/efficacy in early stage human trials, utilising healthyvolunteers. The KLH test can be used to identify pharmacologically active dose of investigational drugs to inform follow on Phase II trial designs in target patient populations.

Autoimmune opportunity as large as oncology. The rationale supporting IMM's approach to autoimmune disease with a LAG-3 agonist (IMP761) has already been supported in published literature, demonstrating key involvement of LAG-3 signalling. IMP761 provides potential to be a disease modifying solution as opposed to current approaches that block mediators further downstream in the immune/inflammatory pathway (i.e. Humira). Abbvie's blockbuster Humira is a relevant predicate when thinking about the end market opportunity for IMP761 should it demonstrate efficacy at correcting immune response, noting that Humira has totalled ~US\$20B sales across key autoimmune indications annually (incl. \$6B in rheumatoid arthritis).

#### Earnings implications

No immediate changes, but we begin to build out potential market models for major autoimmune indications (notably rheumatoid arthritis) to identify opportunity sizing for IMP761 in the event of positive Phase I data in the coming year.

# Investment view

Maintain OVERWEIGHT and our risked \$0.90/sh PT, noting this does not yet include any attribution for IMP761. The next material catalysts for IMM include; a) announcement of their finalised trial design (and potential partner) for the TACTI-004 1L mNSCLC Phase III program (2Q'24); and b) topline data from Phase IIb TACTI-003 trial in 1L mHNSCC (~3Q'24). Unrisked PT at \$6.09/sh.

### Recommendation

**OVERWEIGHT** 

#### Dr Melissa Benson

melissa.benson@wilsonsadvisory.com.au Tel. +61 2 8247 6639

#### Dr Shane Storey

shane.storey@wilsonsadvisory.com.au Tel. +61 7 3212 1351

#### Madeleine Williams

madeleine.williams@wilsonsadvisory.com.au Tel. +61 3 9640 3834

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# | Wilsons Advisory contact

For more information please phone: 1300 655 015 or email: publications@wilsonsadvisory.com.au

