

Immutep Ltd (IMMP)

Positive Signals in Pre-Clinical Studies with IMP-761

After the close, Immutep (Nasdaq: IMMP) hosted a conference call to discuss initial pre-clinical data from their IMP-761 program in development for autoimmune disease. As a reminder, IMP-761 is a first-in-class humanized monoclonal agonist antibody targeting LAG-3. *In vivo* testing was done in a delayed-type hypersensitivity model in cynomolgus monkeys. The data showed a strong reduction in inflammatory T-cell infiltration at tuberculin test sites in monkeys that were vaccinated with BCG antigen and treated with IMP-761 prior to the test. Treatment with IMP-761 showed reductions in both CD3⁺ and CD8⁺ T-cell infiltration. Although preclinical data, the positive signal was good to see as it indicates potential for IMP-761 in autoimmune disease. Looking ahead, management anticipates completing pre-clinical work on IMP-761 in ~18 months and expects to bring the clinical candidate through Phase II development in-house.

- The Role of LAG-3 in Autoimmune Disease.** As a reminder, LAG-3 is implicated to be a checkpoint molecule involved in the negative regulation of T-cell activation. LAG-3 is one of the few markers identified to-date that is solely present on the surface of activated T-cells making it an attractive therapeutic target. Furthermore, high levels of LAG-3 expression is thought to be a marker of T-cell exhaustion following chronic activation, as has been shown in various cancer models and models of chronic infection. We note that targeting LAG-3 in autoimmunity could in theory be overly immunosuppressive from an overcorrection effect. However, the notion that exhausted phenotype T-cells express higher levels of the marker could translate to preferential targeting of autoreactive T-cells. Taking this into account, the level of immunosuppression will depend on the T-cell specificity and the durability of the T-cell response. Overall, we believe further clinical investigation of the agent is warranted.
- IMP-761 Demonstrates Potent Immunosuppression.** IMP-761 demonstrated inhibition of CD8⁺ T-cell proliferation *in-vitro* in human peripheral blood mononuclear cells exposed to a CMV, EBV and influenza peptide pool. Following exposure to the CEF pool, 36.3% of the CD8⁺ population was dividing, which decreased to only 8.6% when PMBCs were exposed to CEF + IMP-761, as shown in **Figure 1**. *In vivo* studies were conducted in 18 male cynomolgus monkeys that were vaccinated with BCG antigen against tuberculosis. Management noted that cynomolgus monkeys were used secondary to an absence of a surrogate antibody for mouse LAG-3. Investigators then measured the inflammatory response following a tuberculin test. 6 monkeys were additionally treated with IMP-761 prior to a second tuberculin test. As shown in **Figure 2**, IMP-761 treated monkeys showed a prominent decrease in inflammatory CD3⁺ and CD8⁺ T-cell infiltration.

These data suggest potential for IMP-761 to curb the immune reaction in autoimmune conditions. Although there are parallels between infectious models and autoimmune disease given that both are associated with a state of chronic immune activation and T-cell exhaustion, we note that multiple studies have shown differences in the underlying balance of co-inhibitory and co-stimulatory signals that shape these conditions, suggesting different immune mechanisms at play. Therefore, we look forward to seeing further pre-clinical evidence for IMP-761 in models of autoimmunity.

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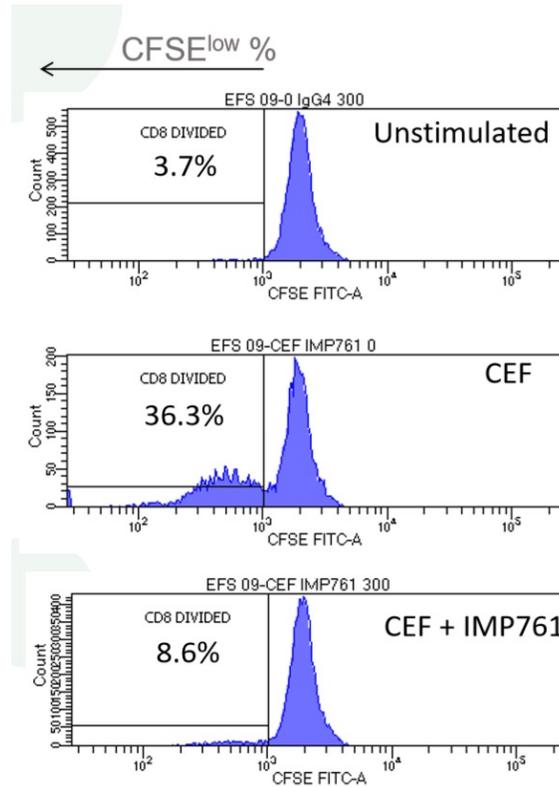
Market Data

Price	\$2.40
Market Cap (M)	\$81
EV (M)	\$55
Shares Outstanding (M)	33.8
Fully Diluted Shares (M)	43.7
Avg Daily Vol	247,518
52-week Range:	\$1.70 - \$4.21
Cash (M)*	\$18.7
Net Cash/Share	\$0.60
Annualized Cash Burn (M)	\$12.5
Years of Cash Left	1.5
Debt (M)	\$0.0
Short Interest (M)	0.11
*	

Financials

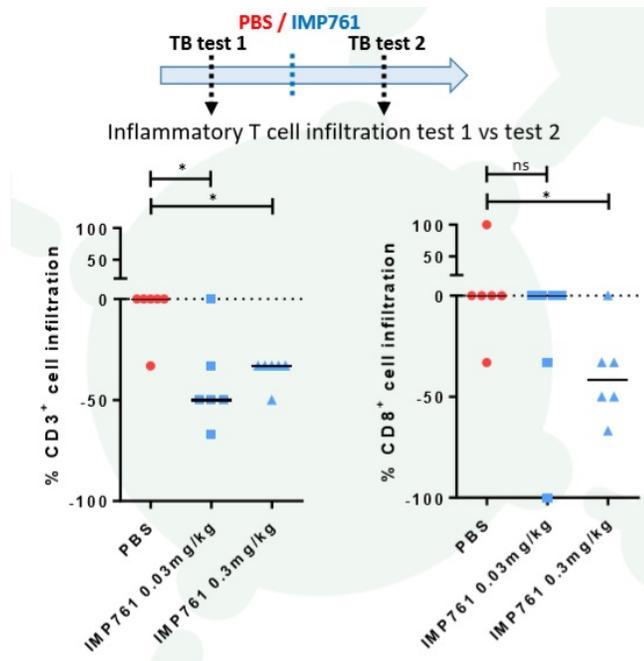
FY Jun		2017A	2018A	2019A
EPS	H1	(0.19)	(0.18)	NA
	H2	NA	NA	NA
	FY	(0.41)	(0.49)	NA

Figure 1. In Vitro Inhibition of CD8+ T-cell Proliferation by IMP-761



Source: Immuteq Presentation

Figure 2. IMP-761 Results in Reductions of Inflammatory T-cell Infiltration



Source: Immuteq Presentation

Expected Upcoming Milestones

- Early 2019 – Initiation of TACTI-002 in HNSCC/NSCLC.
- Q1 2019 – Initiation of INSIGHT-004 in advanced solid malignancies.
- H2 2019 – Primary progression free survival data from AIPAC in TNBC.

Risk to Investment

We consider an investment in Immutep to be a high-risk investment. Immutep is a development stage company with no history of taking a treatment to market, and currently with no FDA approved drugs in its portfolio. There are several other companies trying to target the same indications as Immutep, and the cancer treatment pipeline is especially crowded with competitors. Immutep lead program has not yet generated pivotal data and has limited clinical data to date. Furthermore, early indications of efficacy do not necessarily translate into positive late-stage results. As with any company, Immutep may be unable to obtain sufficient capital to fund planned development programs. There are regulatory risks associated with the development of any drug and Immutep may not receive FDA approval for its candidates despite significant time and financial investments. Regulatory approval to market and sell a drug does not guarantee that the drug will penetrate the market, and sales may not meet the expectations of investors.

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