IMV Inc.

Still Early Days For Basket Trial, But Hints Of Coupled Immune-Tumor Response Are Consistent With DPX-Survivac Action

IMV-TSX: $3.59
Speculative Buy
$12.25 Target

Event: NS-based immune therapy developer IMV provided an update on the firm's 184-patient Phase II basket trial this morning at the ongoing European Society for Medical Oncology (ESMO) meeting. New data were from a limited data set of evaluable subjects (19 of 23 enrolled subjects were evaluable for tumor response and immunological response to therapy) and with variable duration of follow-up, so any early conclusions from this 184-patient Phase II solid tumor study are necessarily interim and malleable. As we will describe below, we believe there were sufficient hints of tumor response and/or stable disease associated with immunological response, at least in ovarian cancer for which IMV already generated encouraging interim DPX-Survivac monotherapy data in the ongoing DeCide trial. We are **maintaining our Speculative BUY rating and PT of $12.25 on IMV**.

Patient recruitment indicates population is heavily advanced in disease burden so any efficacy signals should be viewed favourably: Recall the trial was focused on the treatment of patients with advanced and metastatic solid tumours across five indications (indications include Ovarian Cancer (OvaCa), Hepatocellular Carcinoma (HCC), Non-small Cell Lung Cancer (NSCLC), Bladder Cancer (BlCa), Microsatellite Instability-High (MI-HIGH)) using IMV's flagship survivin-targeted cancer immune therapy DPX-Survivac, as well as Merck's (MRK-NY, NR) humanized anti-PD-1 IgG4 mAb formulation pembrolizumab (brand name: Keytruda) and low-dose cyclophosphamide. The primary endpoint of the trial focuses on efficacy via the objective response rate (ORR) out to 24 months, while select secondary endpoints focused on progression free survival (PFS), overall survival (OS), disease control rate, and duration of response, with all endpoints out to 24 months as well. The trial is slated for completion by YE2022, though we anticipate further updates as the trial advances into further patient enrolment and longer-term treatment progress.

At time of presentation, the firm noted that 19 patients have been treated with the combination therapy. We observed from the baseline demographics in 15 patients surveyed that at least a third of patients have undergone more than four lines of prior therapy before participating in this trial, with the remaining majority of patients having undergone at least one to three lines of therapy. Because IMV's basket study does not have control arm, nor are DPX-Survivac or pembrolizumab being tested as monotherapies in separate study arms, it will be challenging to assess relative tumor response contribution from either drug in isolation or in comparison to alternative therapies.

Accordingly, interpretive capacity of the basket trial will be necessarily limited by those two design elements, but that said, the objective of the trial will be to ascertain if DPX-Survivac confers measurable survivin-targeted T-cell immune response in patients experiencing tumor response and if so, we would see that as credible evidence for therapeutic benefit from this DepoVax formulation. With expectations thus tempered, now as before, we provide our commentary on IMV's new DPX-Survivac Phase II solid tumor data below.

Still early days for signals of efficacy: So on response data, the firm noted that the first two subjects with ovarian, non-small cell lung and bladder cancer have experienced partial responses, while the remaining 19 out of the 23 patients remain active on study treatment. Observing the response data presented (see Exhibit 2), we note that most observations

Projected Return: 241%
Valuation: NPV, 20x EPS, 12.5x EV/EBITDA (25% disc rate, F2024 forecasts)

Market Data

Basic Shares O/S (M)	50.6
Market capitalization ($M)	161.5
Enterprise Value ($M)	142.7
Cash ($M, most rec Q)	26.9
Total debt ($M, most rec Q)	8.1
52 Week Range	$3.06-$8.49
Avg. Daily Volume (M)	0.2129
Fiscal Year End	Dec-31

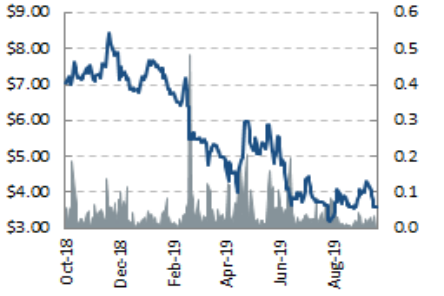
Milestone Watch

Phase II update, DPX-Survivac (Basket solid tumor trial)	FQ419
Phase I update, DPX-E7 (HPV cancers)	FH120
Phase II update, DPX-Survivac (DLBCL,	FQ219
Phase II update, DPX-Survivac (ovarian cancer, with pembrolizumab)	FQ219
Interim Phase I/II DPX-Survivac ovarian cancer (last update Nov/18	FQ418
Phase I, DPX-Survivac (Completed)	FQ216
Phase I, DPX-RSV (Completed)	FQ216

Financial Metrics

In C$	2022E	2023E	2024E
Total Revenue ($000)	5,000	17,920	103,529
EBITDA ($000)	(14,674)	(1,004)	85,977
Adj net inc ($000)	(16,564)	(2,894)	67,269
EPS (basic)	($0.33)	($0.06)	$1.33
EPS (FD)	($0.31)	($0.06)	$1.28
P/E	*NA*	*NA*	*0.0x*
EV/EBITDA	*NA*	*NA*	*0.0x*

IMV is a clinical stage biotechnology firm whose main Depovax lipid-based water-free antigen delivery technology is focused initially on oncology & infectious disease. Lead candidates DPX-Survivac & DPX-RSV advancing well in Phase I/II testing.



Source: Consensus Data - FactSet, Forecasts/Estimates - Echelon Wealth Partners

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occured between study days 49 to 70 (between one to two months out), with two responses now recorded out to study day 133 (~four months out). On days 49 to 70, we observed 7 progressive disease (PD), 4 stable disease, and two partial regressions mainly from patients with ovarian cancer (with or without cyclophosphamide added to the combination regimen). As for overall changes in target lesions, the indications which experienced the greatest reductions were patients with bladder cancer, and ovarian cancer.

Separately, the firm also provided a portrait of tumour infiltration data showing that treatment enhanced the diversity of tumour infiltrating T cells, as observed in biopsy samples taken from the two ovarian cancer patients (one with cyclophosphamide and one without the treatment added to the existing combination regimen). Out of the two patients, the patient with cyclophosphamide added to the combination regimen experienced larger folds in on-treatment versus pre-treatment changes in the diversity of tumour infiltrating T cells. Other than the having the highest change in PD-L1 positive cells targeted by treatment, the patient also experienced higher regulatory T cells FoxP30, CD3 T cells, and CD8 cytotoxic T-cells.

Exhibit 1. Tumour Infiltration By Multiple Immune Cell Populations Observed in Selected Ovarian Cancer Patients

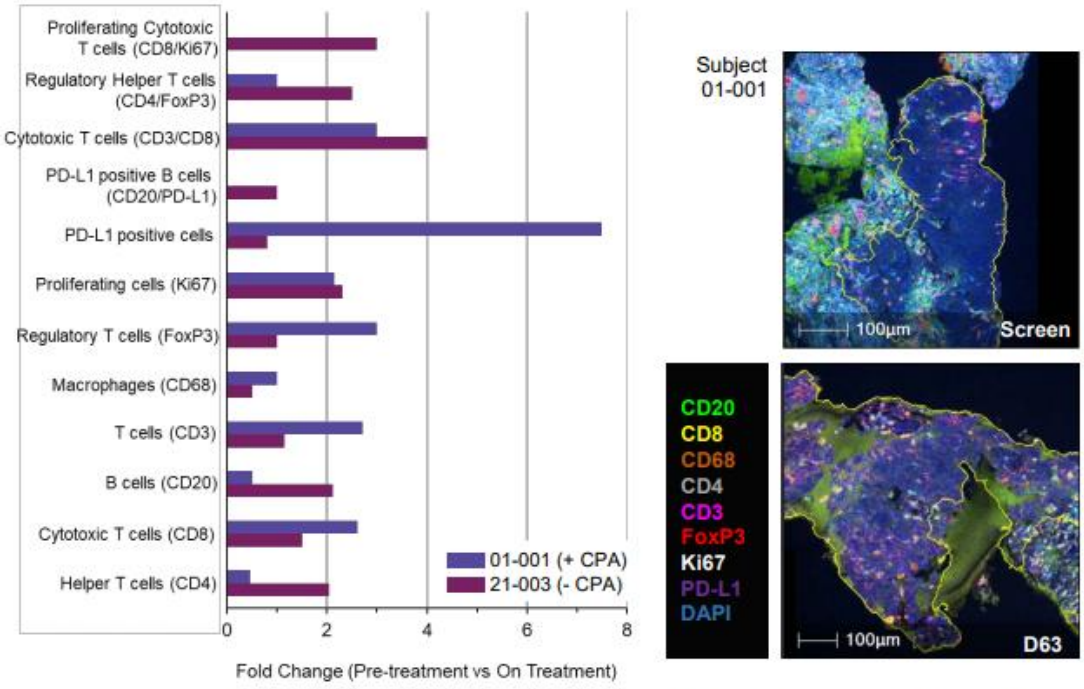

Figure 1: Treatment-induced increases in tumour immune infiltration demonstrated by multiplex IHC. Fold changes in pre-treatment and on-treatment (D56-D70) biomarker infiltration of two OvCa subjects (left) and representative images from one subject (right).

Source: H Conter & coworkers. ESMO (2019) poster presentation (Safety and efficacy results of the combination of DPX-Survivac, pembrolizumab and intermittent low dose cyclophosphamide (CPA) in subjects with advanced and metastatic solid tumours (preliminary results)

Combination therapy regarded as generally safe despite known severe adverse events typically associated with Keytruda: The most common safety event observed was an injection site reaction in both groups of patients (2 out of 4 patients in the DPX-Survivac and pembrolizumab arm, and 9 out of 11 patients in the DPX-Survivac, pembrolizumab and low-dose cyclophosphamide arm). We observed from the general portrait of safety events described in the poster that most appear to be relatively mild events reported (examples include fatigue, and influenza like illness), which remains relatively less severe than other known adverse events (colitis, pneumonitis, and liver problems as examples) associated with Keytruda and were not observed in this trial. Generally with immune system modifying therapies, the severity of adverse events tend to intensify throughout treatment but we were encouraged by just how mild events reported to date are, implying the safety advantage that DPX-Survivac and its combination components have so far exhibited over the more novel immunotherapies approved to date.

Keytruda data also presented at ESMO, with safety data painting a highly toxic regimen: While we are also on the topic of Keytruda, we observed that Merck did present data in solid tumours using Keytruda at ESMO as well, and we believe that medical prospects for DPX-Survivac/Keytruda combination therapies will be as impacted by Keytruda's independent clinical history as by DPX-Survivac's clinical history. Keytruda is already FDA-approved in virtually all cancer forms for which it being tested with DPX-Survivac in the basket trial, so Keytruda baseline data in other clinical settings establishes efficacy thresholds that DPX-Survivac/Keytruda combination therapy will need to overcome. We summarize a few key studies below:

Exhibit 2 – Basket Trial Tumor Responses Were Varied To Be Sure, But Hints Of Partial Response/ Stable Disease In Lung/Ovarian/Liver Cancer Did Correlate With T-Cell Tumor Infiltration

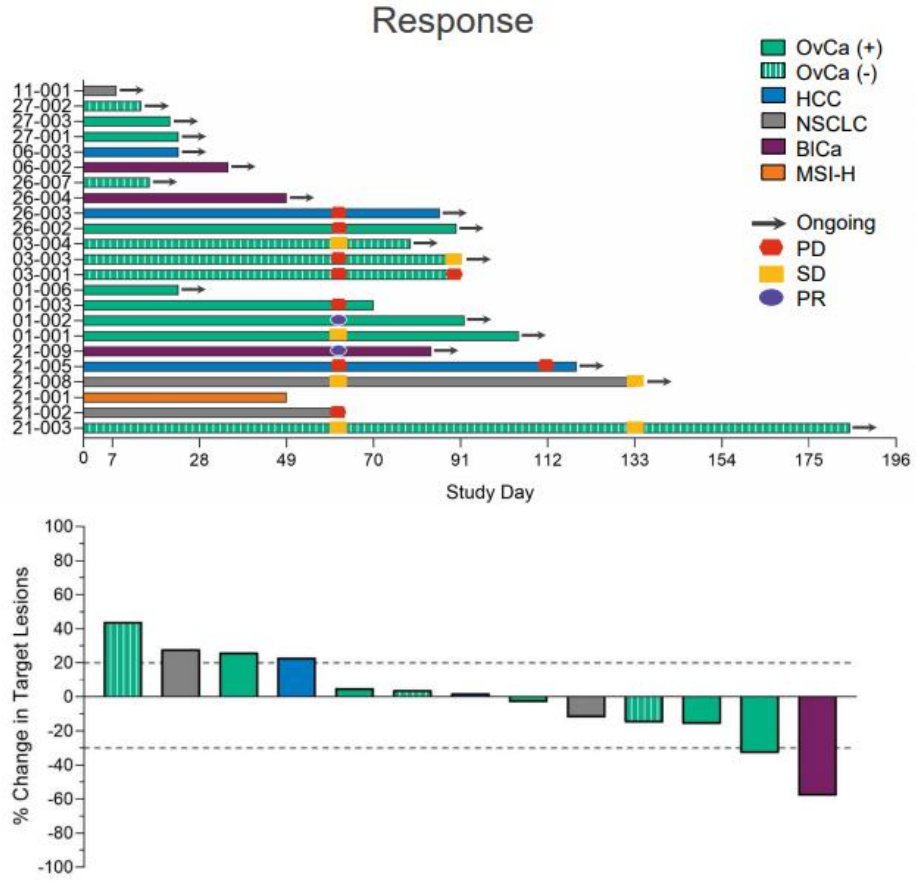

Figure 4: Duration of treatment (top) and waterfall analyses (bottom) of best on-study clinical response by RECIST v1.1 for evaluable study subjects.

Source: H Conter & coworkers. ESMO (2019) poster presentation (Safety and efficacy results of the combination of DPX-Survivac, pembrolizumab and intermittent low dose cyclophosphamide (CPA) in subjects with advanced and metastatic solid tumours (preliminary results)

- **Keytruda performs well with co-administered kinase inhibition in endometrial cancer trial also presented at ESMO 2019:** First, Merck announced that the combination regimen of Keytruda and Eisai's (4523-JP, NR) oral kinase inhibitor Lenvima met the primary endpoint in the 108-patient Phase Ib/II KEYNOTE-146 endometrial cancer trial. The primary endpoint was ORR at week 24, and with the trial assessing patients that had tumours that were not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), although 11 patients surveyed did exhibit those types of tumours. Overall results indicated an ORR at week 24 of 38%, and with data cut-off saw ORR rising to 38.9%. Complete response rate was 7.4%, with partial response rate of 31.5%. Median duration of response was 21.2 months. 9.3% of patients in the combination treatment arm chose to discontinue treatment due to adverse events.

  The trial saw 69.4% of patients experiencing grade 304 treatment-related adverse events. The most common events were hypertension (32.4%), fatigue (8.3%) diarrhea (6.5%), and proteinuria (3.7%). We note in passing that the Lenvima/Keytruda combination regimen has been simultaneously FDA, Health Canada and Australia's

Therapeutic Goods Administration approved since September 18th 2019 under a novel regulatory program Project Orbis between the three countries. The approval was for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- **Keytruda also performs well in new human testing in urothelial/bladder cancer:** Next, a *FierceBiotech* article reported that Astellas (4503-JP, NR)/Seattle Genetics' (SGEN-Q, NR) antibody drug conjugate targeting protein Nectin-4 enfortumab alongside Keytruda nicely showed a 74% reduction in tumours and clearance of 13% of tumours in patients with treatment-naïve advanced urothelial cancer patients. Data comes from a Phase I trial presented at ESMO, with data focusing on 45 patients in such patients, as well as patients who were deemed too frail for first-line treatment with cisplatin. On safety, one patient died from treatment-related multiple organ failure, and with 16% or seven patients experiencing serious treatment-adverse related events, and with four patients (9%) opting to discontinue the trial.

Exhibit 3 – Income Statement & Financial Forecast Data for IMV

Year-end December 31 (C$000, except EPS)	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Licensing and milestone	0	0	0	0	0	0	0	0	0	0	0
Revenue - DPX-Survivac royalties	0	0	0	0	0	12,920	63,990	133,477	187,807	228,498	281,965
Revenue - DPX-RSV royalties	0	0	0	0	0	0	34,539	70,460	107,804	146,614	186,933
Other revenue	483	500	5,000	5,000	5,000	5,000	5,000	5,000	5,000	5,000	5,000
Total revenue	**$483**	**$500**	**$5,000**	**$5,000**	**$5,000**	**$17,920**	**$103,529**	**$208,937**	**$300,612**	**$380,111**	**$473,897**
Revenue growth (%)	*NA*	*NA*	*NA*	*NA*	*NA*	*258%*	*478%*	*102%*	*44%*	*26%*	*25%*
Operational expenses	19,526	24,105	24,302	19,462	19,674	18,924	17,553	16,313	15,192	14,179	13,261
EBITDA	**($19,043)**	**($23,605)**	**($19,302)**	**($14,462)**	**($14,674)**	**($1,004)**	**$85,977**	**$192,624**	**$285,419**	**$365,933**	**$460,636**
EBITDA growth (%)	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*124%*	*48%*	*28%*	*26%*
EBITDA margin (%)	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*83.0%*	*92.2%*	*94.9%*	*96.3%*	*97.2%*
Non-operating expenses	$1,507	$1,075	$1,075	$1,075	$1,075	$1,075	$1,075	$1,075	$1,075	$1,075	$1,075
Net interest expense (income)	$1,385	$815	$815	$815	$815	$815	$815	$815	$815	$815	$815
Net income, fully-taxed	($21,935)	($25,495)	($21,192)	($16,352)	($16,564)	($2,894)	$67,269	$152,587	$226,823	$291,234	$366,997
Fully-taxed EPS (basic)	($0.49)	($0.50)	($0.42)	($0.32)	($0.33)	($0.06)	$1.33	$3.02	$4.48	$5.76	$7.25
Fully-taxed EPS (fd)	**($0.47)**	**($0.48)**	**($0.40)**	**($0.31)**	**($0.31)**	**($0.06)**	**$1.28**	**$2.90**	**$4.31**	**$5.54**	**$6.98**
P/E (basic)	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*3.7x*	*1.6x*	*1.1x*	*0.9x*	*0.7x*
EV/EBITDA	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*1.7x*	*0.7x*	*0.5x*	*0.4x*	*0.3x*

Source: Historicals – company information, forecasts/estimates — Echelon Wealth Partners

- **Keytruda rebounds from previous setbacks in breast cancer to exhibit solid responses in pre-surgical patients:** Keytruda also reported positive results in early-stage triple negative breast cancer (TNBC) under neoadjuvant and adjuvant settings. The therapy met one of the dual primary endpoints in the Phase III KEYNOTE-522 trial evaluating Keytruda with chemotherapy in TNBC. An interim analysis found that Keytruda with chemotherapy demonstrated a statistically significant improvement from 51.2% in neoadjuvant chemotherapy to 64.8% in pathological complete response (defined by no invasive cancer in breast and lymph nodes) as compared to chemotherapy alone regardless of PD-L1 status.

- **Keytruda lung cancer data are equally impressive:** Lastly, Merck reported data from the Phase III KEYNOTE-407 trial evaluating Keytuda with chemotherapy in non-small cell lung cancer (NSCLC). Data indicated that the median OS was 15.9 months in patients given pembrolizumab and 11.3 months in patients on placebo, while PFS was a median of 6.4 months in the pembrolizumab arm as compared to 4.8 months in the control arm. As for treatment response, 57.9% of patients in the pembrolizumab arm reported response as compared to 38.4% of patients in the placebo arm, and with a median duration of 7.7 months and 4.8 months respectively. On safety, 69.8% of patients treated with pembrolizumab reported grade 3 or more severe adverse events, as compared to 68.2% of patients in placebo arm. Grade 3 events included pneumonitis (inflammation of the lung tissue) and autoimmune

hepatitis, as well as immune-mediated events and infusion reactions. In both arms, one patient each died from pneumonitis.

With a preliminary update on the basket trial now in the public domain, we await other H219 milestones from IMV including topline results from the ongoing 16-patient Phase II trial evaluating DPX-Survivac as a monotherapy in ovarian cancer patients (ahead of trial completion by YE2020; with primary endpoint data focusing on ORR out to 13 months), and separately, an update on clinical data from an investigator-sponsored 25-patient Phase II trial evaluating DPX-Survivac with Merck's Keytruda in Diffuse Large B-Cell Lymphoma (trial completion anticipated by May/21, with top line results expected by H120).

Exhibit 4 – Valuation Scenarios for IMV

NPV, discount rate	15%	20%	25%	30%	35%	40%
Implied value per share	$25.70	$17.94	**$12.15**	$9.00	$6.42	$4.57
Price/earnings multiple, F2024	**10x**	**15x**	**20x**	**25x**	**30x**	**40x**
Implied share price [1]	$6.81	$10.21	**$13.61**	$17.02	$20.42	$27.23
EV/EBITDA multiple, F2024	**5x**	**10x**	**12.5x**	**20x**	**25x**	**30x**
Implied share price [1,2]	$4.18	$8.37	**$10.46**	$16.74	$20.92	$25.11
One-year IMV target price (C$) [1]			**$12.08**			

[1] *Based on F2024 fully-taxed EPS est of $1.33; EBITDA of $86.0M, discounted at 25%; fd S/O of 52.6M post-consolidation*

[2] *EV incorporates FQ219 cash of $26.9M, total debt of $8.1M*

Source: Forecasts/Estimates - Echelon Wealth Partners

Summary and valuation: For now, **we continue to maintain our $12.25 price target and Speculative BUY rating on IMV**. Our price target is the average of three methodologies: NPV (25% discount rate), and multiples of our F2024 EBITDA/fd EPS forecasts ($86.0M/$1.33, respectively), predominantly driven by DPX-Survivac economics. Our EV incorporates FQ219 cash of $26.9M, total debt of $8.1M (much of which is low-to-no-interest government loans), and fully-diluted S/O of 52.6M. At current share price, our PT corresponds to a one-year return of 241%.

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Company: IMV Inc. | IMV:TSX
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Buy	The security represents attractive relative value and is expected to appreciate significantly from the current price over the next 12 month time horizon.
Speculative Buy	The security is considered a BUY but in the analyst's opinion possesses certain operational and/or financial risks that are higher than average.
Hold	The security represents fair value and no material appreciation is expected over the next 12-18 month time horizon.
Sell	The security represents poor value and is expected to depreciate over the next 12 month time horizon.
Under Review	While not a rating, this designates the existing rating and/or forecasts are subject to specific review usually due to a material event or share price move.
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-Dropped Coverage	Applies to former coverage names where a current analyst has dropped coverage. Echelon Wealth Partners will provide notice to investors whenever coverage of an issuer is dropped.

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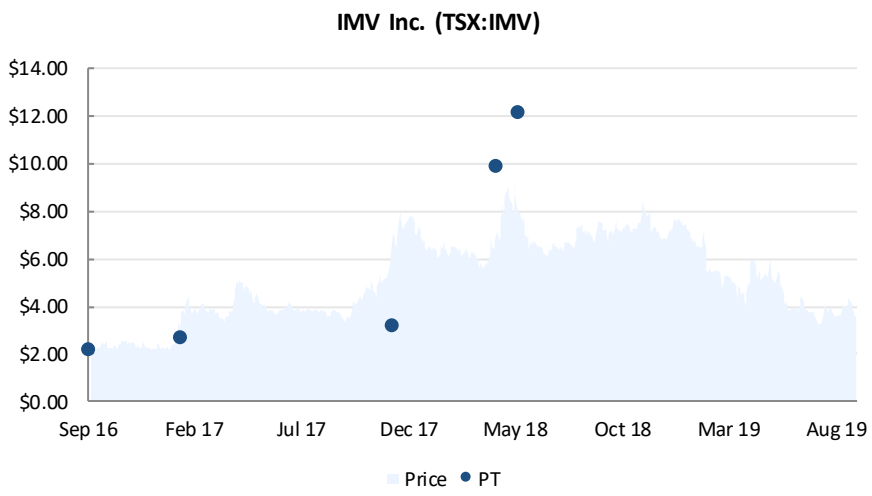
Recommendation Hierarchy	Buy	Speculative Buy	Hold	Sell	Under Review	Restricted	Tender
Number of recommendations	52	42	16	0	7	0	2
% of Total (excluding Restricted)	44%	36%	14%	0%	6%		
Number of investment banking relationships	13	16	4	0	2	0	0
% of Total (excluding Restricted)	37%	46%	11%	0%	6%		

PRICE CHART, RATING & PRICE TARGET HISTORY



Date	Target (C$)	Rating
30 Sep 2016	$2.25	Spec Buy
6 Feb 2017	$2.75	Spec Buy
5 Dec 2017	$3.25	Spec Buy
3 May 2018	$10.00	Spec Buy
4 Jun 2018	$12.25	Spec Buy

Coverage Initiated: Sep 30, 2016

Data sourced from: FactSet

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