

**Drug Pipeline:
Latest on COVID-19 Vaccines
& Other Key Therapies**

Mike Sullivan
Cubic Health Inc.



COVID-19 Update

Interim results of the SOLIDARITY Therapeutic Trials proved **little to no impact** on 28-day mortality or in-hospital course of COVID-19 on hospitalized patients taking:

- Remdesivir (Veklury)
- Hydroxychloroquine
- Lopinavir & Ritonavir (Kaletra)
- Interferon



COVID-19 Update

- Road to a vaccine is likely to be longer than hoped
- Vaccine Pipeline:
 - > **90** Vaccine candidates at pre-clinical stage
 - **40** Vaccine candidates in Phase 1 or 2
 - **Only 11 Vaccine candidates have made it to Phase 3**
 - No Phase 3 trials currently taking place in Canada



COVID-19 Update

- High profile delays in recent weeks related to Phase 3 trials with candidates from AstraZeneca, Johnson & Eli Lilly
- Highlights challenges in successful vaccine development and why safety evaluations need to be taken seriously
- Challenges ahead related to efficacy (50%+), scaling manufacturing, global distribution and priority



COVID-19 Consideration for Employers

- Highly unlikely a vaccine is widely distributed in 2021
- Seroprevalence in Canada is very low
- Current environment extending through 2021
- First generation vaccine(s): reducing severity or reducing transmission (or both)?
- Efficacy & distribution



Drug Pipeline Update

Drugs under review by Health Canada in October 2020:

- Cancer Specialty Drugs: 7
- Orphan Drugs (Rare Diseases): 9
- Non-Cancer Specialty Drugs: 10
- Biosimilars: 9
- Non-Specialty Drugs: 24

High-cost specialty drugs: **60% of pipeline therapies** under review and the vast majority of expected cost pressures



Drug Pipeline Update – Cancer Drugs

DRUG	INDICATION	ESTIMATED COST
Fedratinib (Approved)	Myelofibrosis	\$6,300 USD/month
Sonidegib (Approved)	Basal Cell Carcinoma	\$14,200 USD/month
Tucatinib (Approved)	HER2+ Breast Cancer (Approved in 4 months)	\$18,500 USD/month
Ripretinib (Approved)	Gastrointestinal Stromal Tumors	\$32,000 USD/month
Binimetinib	Metastatic Melanoma (with Encorafenib)	\$7,000-\$9,700 CAD/month
Encorafenib	Metastatic Melanoma (with Binimetinib)	\$6,900-\$9,900 CAD/month
Pertuzumab/Trastuzumab	HER2+ Breast Cancer	\$55,000 - \$150,000 USD
Trastuzumab deruxtecan	Breast Cancer & Gastric Cancer	\$11,000 USD every 3 weeks



Drug Pipeline Update – Orphan Drugs

DRUG	INDICATION	ESTIMATED COST
Tafamidis (Marketed)	Cardiomyopathy	\$195,000 CAD/year
Amifampridine (Approved)	Lambert-Eaton Myasthenic Syndrome	\$280,000 USD/year
Satralizumab (Marketed)	Neuromyelitis Optica Spectrum Disorder	\$600,000 CAD/year
Mecasermin	Growth Failure (ILG-1 Factor 1 Deficiency)	\$190,000 USD /year
Luspatercept	Anemia (Beta-Thalassemia and MDS)	\$210,000 USD/year
Voretigene neparvovec	Retinal Dystrophy	\$850,000 USD



Drug Pipeline Update – Orphan Drugs

DRUG	INDICATION	ESTIMATED COST
Onasemnogene abeparvovec	Spinal Muscular Atrophy	\$2,100,000 USD (single treatment)
Trientine	Wilson Disease	\$273,000 USD/year
Emapalumab	Primary Hemophagocytic Lymphohistiocytosis	\$300,000+ USD/year
Givosiran	Acute Hepatic Porphyria	\$560,000 USD
Triheptanoin	Long-Chain Fatty Acid Oxidation Disorders	\$138,000 USD
Fostamatinib disodium	Chronic Immune Thrombocytopenia	\$175,000 USD



Drug Pipeline Update – Specialty Drugs

DRUG	INDICATION	ESTIMATED COST
Esketamine (Marketed)	Treatment Resistant Depression (TRD)	\$14,200 - \$42,588 CAD/year
Roxadustat	Anemia – Chronic Kidney Disease	\$35,000+ CAD/year
Tildrakizumab	Plaque Psoriasis	\$58,000 USD/year
Ozanimod	Relapsing MS	\$34,000 CAD/year
Eptinezumab	Migraine Prophylaxis	\$7,000 - \$20,000 USD/year
Filgotinib	Rheumatoid Arthritis & Crohn's	\$20,000 CAD/year
Ofatumumab	Relapsing MS	\$65,000 USD/year
Pitolisant	Narcolepsy	\$4,200 - \$12,800 CAD/year
Ponesimod	MS & Psoriasis	\$34,000 CAD/year
Solriamfetol	Narcolepsy & Obstructive Sleep Apnea	\$9,600 USD/year



Notable New Entrants in 2020

DRUG	INDICATION	ESTIMATED COST
Polatuzumab	B-cell Lymphoma	\$99,000 USD
Isatuximab	Relapsed & Refractory Multiple Myeloma	\$127,400 USD/year
Glasdegib	Acute Myeloid Leukemia (AML)	\$203,100 USD/year
Caplacizumab	Thrombotic Thrombocytopenic Purpura (TTP)	\$270,000 USD/episode
Alpelisib	HR+ HER- Metastatic Breast Cancer	\$201,500 USD/year
Entrectinib	ROS1+ Metastatic NSCLC	\$204,000 USD/year
Darolutamide	Prostate Cancer	\$168,600 USD/year
Siponimod	Secondary Progressive MS	\$34,200 CAD/year
Gilteritinib	Relapsed & Refractory AML	\$27,000 USD/month



Drug Pipeline Update – Specialty Drugs

Esketamine Nasal Spray

- First therapy indicated for **Treatment Resistant Depression**
- For many plans: ~15% of all claiming members are treating Depression and **1-2% are managing TRD**
- Annual Cost: \$14,196 to \$42,588/year (for maintenance)



Drug Pipeline Update – Expanded Use

Cost pressures also from expanding indications:

1) Soliris®

Indication 1: Paroxysmal Nocturnal Hemoglobinuria (2009)

Indication 2: Atypical Hemolytic Uremic Syndrome (2013)

Indication 3: Generalized Myasthenia Gravis (2018)

Indication 4: Neuromyelitis Optica Spectrum Disorder (2019)



Drug Pipeline Update – Expanded Use

2) Keytruda®

Original Market Date July 2017 – **now up to 14 indications:**

- Classical Hodgkin Lymphoma, Primary Mediastinal B-Cell Lymphoma
- Unresectable or metastatic Colorectal or Endometrial Cancer
- Unresectable or metastatic Melanoma without prior treatment or following previous therapy
- Adjuvant treatment of patients with Stage III Melanoma
- Metastatic Non-Small Cell Lung Carcinoma (monotherapy)
- Metastatic non-squamous NSCLC (combination)
- Locally advanced or metastatic Urothelial Carcinoma
- Advanced or metastatic Renal Cell Carcinoma

Under HC Review for Recurrent or Metastatic Head & Neck Squamous Cell Carcinoma



Drug Pipeline Update – Recent Examples

3) Dupixent®

- Initially approved for the treatment of Severe Atopic Dermatitis
- Recently approved for Rhinosinusitis with Nasal Polyposis
- Approved for the management of Asthma in the US



Drug Pipeline Update

Factors affecting rate & extent of drug pipeline impact on plans:

- Project Orbis - Cancer Pipeline – 4 Month review for Tucatinib
- Aligned review with Health Technology Assessments
- Distribution and administration considerations (Esketamine)
- “Hospital Use Only” determinations
- Length of time between HC approval and Product Marketing
- **PMPRB & Amendments to Patented Medicines Regulations**



Patented Medicines Regulations

Amendments to Patented Medicines Regulations published Aug 2019

– Scheduled to come into force January 1, 2021

Significant changes include:

- 1) Additional price regulatory factors – pharmacoeconomic analysis
- 2) Revised schedule of comparator countries

Latest version of PMPRB Draft Guidelines published June 2020

Final Guidelines expected soon but significant uncertainties remain in terms of implementation and length of transitional periods.




Drug Pipeline Implications

What are implications of existing specialty meds & pipeline on:

- Cost-shifting from public to private sector
- Delays on approvals pushing therapies to private sector
- Feasibility of National Pharmacare (universal first payer)
- Plan contract language
- Existing Prior Authorization protocols





Mike Sullivan
CEO & Co-Founder
Cubic Health Inc.
msullivan@cubic.ca

