

## Examples of New Medicine Availability in the United States vs. Other High-Income OECD Countries

### AIMOVIG® (erenumab-aooe)

- AIMOVIG® is the first treatment for the prevention of migraines in adults, reducing the number of days per month that patients experience migraines, with many patients achieving at least a 50 percent reduction.
- While AIMOVIG® has been available to chronic migraine sufferers in the United States for nearly three years, the product is still not available in many high-income OECD countries, including France, Japan and the Netherlands.
- Although AIMOVIG® has launched in other countries including Australia and Canada, it is not reimbursed by government insurance.

AIMOVIG®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	May 2018	✓	✓	✗	✓	✓	✓	✗	✓	✓	✓	✗	✗	✓	✓	✓	✓
Lag in Months from First Launch		0	5	4		7	5	4		6	8	7			2	2	3	3

### AYVAKIT® (avapritinib)

- AYVAKIT® is the first-of-its-kind targeted therapy to treat a rare form of gastrointestinal cancer, with nearly 85 percent of patients achieving complete or partial tumor shrinkage, lasting six months or longer.
- While AYVAKIT® has been available to cancer patients in the United States for more than a year, cancer patients in other high-income OECD countries (with the exception of Germany) still do not have access.

AYVAKIT®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Jan 2020	✗	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗	✗	✗	✗	✗
Lag in Months from First Launch		0								10								

### BENLYSTA® (belimumab)

- BENLYSTA® is the first new medicine approved to treat lupus patients in more than 50 years, showing improvement in symptoms and slower disease progression.
- While BENLYSTA® is now available across high-income OECD countries, lupus patients in the United States had access three years before patients in Australia and almost seven years before patients in Japan.
- Although BENLYSTA® launched on the Canadian market shortly after it launched in the United States 10 years ago, the product is not reimbursed by government insurance in Canada.

BENLYSTA®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Mar 2011	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Lag in Months from First Launch		0	37	6	16	5	5	5	6	5	21	24	82	4	5	5	16	6

### BLINCYTO® (blinatumomab)

- BLINCYTO® is a breakthrough treatment for a rare and rapidly progressing form of leukemia. Within two cycles of treatment with BLINCYTO®, 42 percent of patients achieve remission.
- Although BLINCYTO® is available across high-income OECD countries, patients in the United States had access to the drug an average of 19 months earlier than patients in other countries and 4 years earlier than patients in Japan.

BLINCYTO®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Dec 2014	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Lag in Months from First Launch		0	22	13	40	15	12	12	16	12	15	27	48	11	15	11	17	12

### BRINEURA® (cerliponase alfa)

- BRINEURA® is the first-and-only breakthrough treatment for Batten disease, a rare neurodegenerative condition with an average life expectancy of only 10 years. Patients treated with BRINEURA® were 13 times less likely to experience declines in their condition.
- Nearly four years after BRINEURA® became available to Batten disease patients in the United States, the product remains unavailable to patients in several high-income OECD countries.
- BRINEURA® has launched in Australia and France but is not reimbursed by government insurance.

BRINEURA®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Jul 2017	✓	✓	✗	✓	✓	✗	✓	✓	✗	✗	✓	✓	✗	✓	✗	✓
Lag in Months from First Launch		0	19	15		18	12		0	2			33	14		12		16

### ERLEADA® (apalutamide)

- ERLEADA® is a ground-breaking treatment for patients with difficult-to-treat prostate cancer, demonstrating a 72 percent reduction in risk of death and median metastasis free period of 24 months.
- ERLEADA® was available to patients in the United States for two years before it became available to patients in most other high-income OECD countries.
- Even in several countries where ERLEADA® has launched – including Australia, Canada, France and the United Kingdom – it is not reimbursed by government insurance.

ERLEADA®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Feb 2018	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Lag in Months from First Launch		0	9	13		5	23	23	7	12	23	23	15	11	23	23	21	11

### IBRANCE® (palbociclib)

- IBRANCE® is a breakthrough therapy for advanced-stage or metastatic breast cancer, halting disease progression for a median of 11 months.
- While IBRANCE® has launched across high-income OECD countries, breast cancer patients in the United States had access to it an average of two-and-a-half years earlier than patients in other countries.

IBRANCE®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Jan 2014	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Lag in Months from First Launch		0	35	30	42	23	30	30	19	30	36	23	43	29	9	29	33	30

### ISTURISA® (osilodrostat)

- ISTURISA® is the first-of-its-kind therapy for patients with Cushing's disease who either cannot undergo pituitary surgery or for whom surgery was not effective.
- While ISTURISA® has been available to patients in the United States for over a year, Cushing's patients in a majority of other high-income OECD countries still do not have access.

ISTURISA®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Mar 2020	✗	✓	✗	✗	✗	✗	✓	✓	✗	✓	✗	✗	✗	✗	✗	✗
Lag in Months from First Launch		0		4					4	4		9						

### KADCYLA® (trastuzumab emtansine)

- KADCYLA® is a game changing “smart bomb” therapy that precisely targets breast cancer cells and leaves healthy cells unharmed, resulting in fewer side effects, tumor shrinkage, slowed disease progression and prolonged survival.
- While breast cancer patients in the United States had access to KADCYLA® in February 2013, patients in other high-income OECD countries waited an average of 12 months for the therapy to launch. Patients in France waited 18 months and patients in Ireland waited two-and-a-half years.

KADCYLA®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Feb 2013	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Lag in Months from First Launch		0	7	12	15	8	11	10	18	11	30	15	14	9	12	9	3	14

### KALYDECO® (ivactafor)

- KALYDECO® is a breakthrough therapy that targets the underlying cause of cystic fibrosis rather than just treat the symptoms. KALYDECO® helps to improve lung function and reduce other symptoms.
- Although KALYDECO® is available in all high-income countries except Japan, patients in the United States had access an average of nearly 2 years earlier.
- Even in some countries where KALYDECO® has launched, such as Canada, patients who rely on government insurance still do not have access.

KALYDECO®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Feb 2012	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓
Lag in Months from First Launch		0	34	16	32	72	8	80	6	6	14	40		5	7	5	7	11

### KEYTRUDA® (pembrolizumab)

- KEYTRUDA® is a game-changing therapy that treats many forms of cancer by enabling the patient's immune system to recognize and fight cancer cells regardless of where in the body they originated.
- Although KEYTRUDA® has now launched across high-income OECD countries, it is not available to many cancer patients for which regulatory authorities have approved indications. For example, in the United Kingdom, KEYTRUDA® is not reimbursed for some patients with renal cancer and Hodgkins Lymphoma.

KEYTRUDA®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Sep 2014	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Lag in Months from First Launch		0	8	12	19	9	11	11	12	11	10	15	29	7	0	10	12	10

### KYMRIA® (tisagenlecleucel)

- As the first CAR-T therapy, KYMRIA® revolutionized cancer treatment by using a patient's own cells to attack their deadly cancer, achieving unprecedented complete remissions in Hodgkin's lymphoma for up to 56 months.
- While KYMRIA® has been available to cancer patients and their families in the United States for over three years, it is still not available to patients in Australia and many other high-income OECD countries.

KYMRIA®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Dec 2017	✗	✗	✓	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓	✗	✗	✓
Lag in Months from First Launch		0			20	20	12	15	7	9		24	17		18			13

### MEPSEVII® (vestronidase)

- Prior to the launch of MEPSEVII®, patients with the rare degenerative metabolic condition called Sly Syndrome had no other approved treatment options. MEPSEVII® not only stabilized, but improved outcomes for these patients.
- While MEPSEVII® has been available to Sly Syndrome patients for nearly four years, with the exception of Germany, patients living in all other high-income OECD countries continue to have no treatment options.

MEPSEVII®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Dec 2017	×	×	×	×	×	×	×	✓	×	×	×	×	×	×	×	×
Lag in Months from First Launch		0								10								

### PALYNZIQ® (pegvaliase-pqpz)

- PALYNZIQ® is a breakthrough treatment for patients with a rare metabolic condition called PKU. Prior to the launch of PALYNZIQ®, no other treatments existed to lessen blood imbalances leading to irreversible brain and nerve damage.
- PALYNZIQ® has been available to PKU patients in the United States for nearly three years. Unfortunately, patients in a majority of other high-income countries including Canada, France, Japan and the United Kingdom still do not have access.

PALYNZIQ®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Jun 2018	×	✓	×	×	×	×	×	✓	×	×	×	×	×	×	×	×
Lag in Months from First Launch		0		13						13								

### PORTRAZZA® (necitumumab)

- PORTRAZZA® is a breakthrough treatment option for patients with a specific form of advanced lung cancer, offering significant improvement in progression-free survival.
- Over five years after PORTRAZZA® became available to patients in the United States, it is still not available to patients in high-income OECD countries including Australia, Canada, France and Switzerland.

PORTRAZZA®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Dec 2015	✗	✓	✗	✗	✓	✓	✗	✓	✗	✗	✓	✓	✓	✓	✗	✓
Lag in Months from First Launch		0		4			6	5		4			48	2	6	5		4

### RUKOBIA® (fostemsavir)

- Designated a breakthrough therapy, RUKOBIA® is the first in a new class of drugs to treat patients living with multi-drug resistant HIV who lack other treatment options. After 24 weeks of treatment, over half of patients taking RUKOBIA® achieved levels of HIV low enough to be considered undetectable.
- While RUKOBIA® has been available to HIV patients in the United States for nearly a year, HIV patients in other high-income OECD countries still do not have access.

RUKOBIA®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Jul 2020	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗
Lag in Months from First Launch		0																



### SPINRAZA® (nusinersen)

- SPINRAZA® is a breakthrough disease-modifying therapy for patients with spinal muscular atrophy (SMA), a progressive degenerating neurological disease.
- While SPINRAZA® is available to SMA patients regardless of disease severity in the United States, it is only available to subsets of patients in other high-income OECD countries. For example, in France, SPINRAZA® is not publicly reimbursed for severe SMA patients.

SPINRAZA®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Feb 2017	✓	✗	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓
Lag in Months from First Launch		0	11		18	6	4	5	4	5		10	6	3	5	3	7	6

### TECENTRIQ® (atezolizumab)

- TECENTRIQ® is a game-changing immunotherapy that can rapidly shrink tumors in patients with a variety of advanced cancers including those of the lung, bladder and breast.
- While TECENTRIQ® is now available across high-income OECD countries, U.S. patients had access to it an average of 18 months earlier than patients in other countries.
- Although TECENTRIQ® has launched in these countries, not all patients have access to it. For example, TECENTRIQ® is not reimbursed for lung cancer patients in Canada and liver cancer patients in Ireland, among others.

TECENTRIQ®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	May 2016	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Lag in Months from First Launch		0	17	18	21	12	18	17	19	17	18	23	23	16	19	16	13	17

### TROGARZO® (ibalizumab-uiyk)

- TROGARZO® is a breakthrough therapy that treats drug-resistant forms of HIV. Prior to its approval, patients had limited treatment options, putting them at a high risk of complications and progression to death.
- While TROGARZO® has been available to HIV patients in the United States for nearly three years, with the exception of France and Germany, patients with drug-resistant forms of HIV in other high-income OECD countries still do not have access to it.

TROGARZO®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Apr 2018	×	×	×	×	×	×	✓	✓	×	×	×	×	×	×	×	×
Lag in Months from First Launch		0							18	29								

### YERVOY® (ipilimumab)

- YERVOY® is the first-of-its kind checkpoint inhibitor, that works by enabling the immune system to recognize, target and attack advanced forms of cancer including melanoma, lung and colorectal.
- While YERVOY® has launched across high-income OECD countries, patients in the United States had access to it five years before patients in Australia and more than four years before patients in Japan.
- Even in countries where YERVOY® launched after the United States (e.g., Australia, Canada and France), the product is not reimbursed by government insurance to treat several forms of cancer.

YERVOY®	First Launch	United States	Australia	Austria	Belgium	Canada	Denmark	Finland	France	Germany	Ireland	Italy	Japan	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Launched	U.S.	Apr 2011	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Lag in Months from First Launch		0	61	28	13	7	4	3	3	4	9	23	53	3	5	3	6	4