

INDUSTRY OVERVIEW

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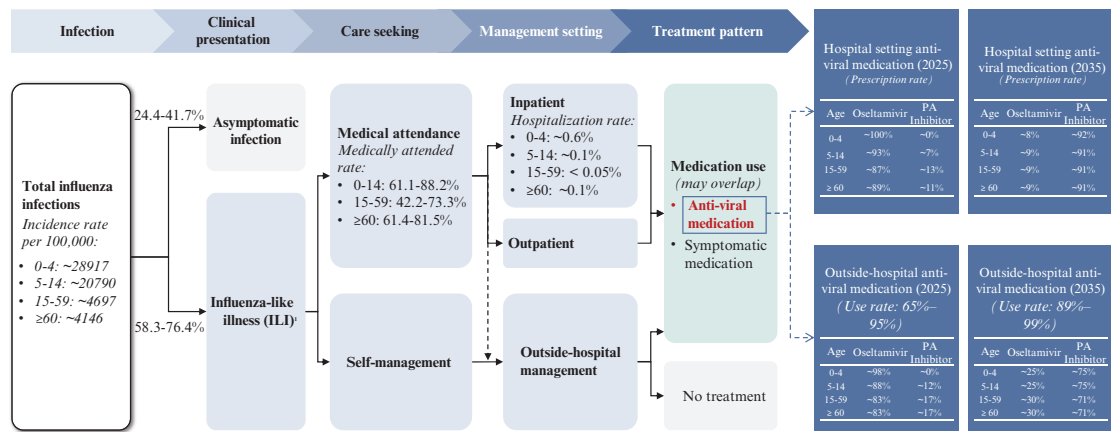
OVERVIEW OF THE MARKET FOR INFLUENZA TREATMENT AND PREVENTION DRUGS

Overview of Influenza Disease

Influenza is an acute respiratory viral infectious disease caused by influenza viruses, transmitted mainly via droplets, aerosols, and contact. Hemagglutinin (“HA”) and neuraminidase (“NA”) on the viral surface serve as key targets for vaccine design. Upon infecting respiratory epithelial cells, the virus replicates and is released. A proportion of infections present as influenza-like illness (“ILI”) defined by fever with respiratory symptoms, with approximately 60% of infections being symptomatic, while severe cases may develop viral pneumonia or secondary bacterial infections. Due to frequent antigenic drift and shift, periodic vaccine updates and booster immunization are required to maintain community protection. Influenza A and B viruses are the principle types of influenza viruses responsible for seasonal epidemics in humans. Influenza A viruses (including subtypes such as H1N1 and H3N2) and influenza B viruses are the predominant circulating strains associated with seasonal influenza infections worldwide.

Epidemiology of Influenza

Overview of Influenza Patient Journey in China



Source: JAMA Netw Open; Int. J. Environ. Res. Public Health; Am J Epidemiol; BMC Infect Dis; Vaccines (Basel); Emerg Infect Dis; Clin Microbiol Infect; Influenza Diagnosis and Treatment Guideline (2025 Edition); Diagnosis and Treatment Protocol for Influenza (2025 Edition, China); Clinical Practice Guidelines for the Treatment and Prophylaxis of Influenza in China (2025 Edition); China CDC; CIC

Note: 1. Among ILI patients, age-based high-risk groups included children aged 0–4 years and older adults aged ≥60 years, accounting for 13.6% and 12.1%, respectively.

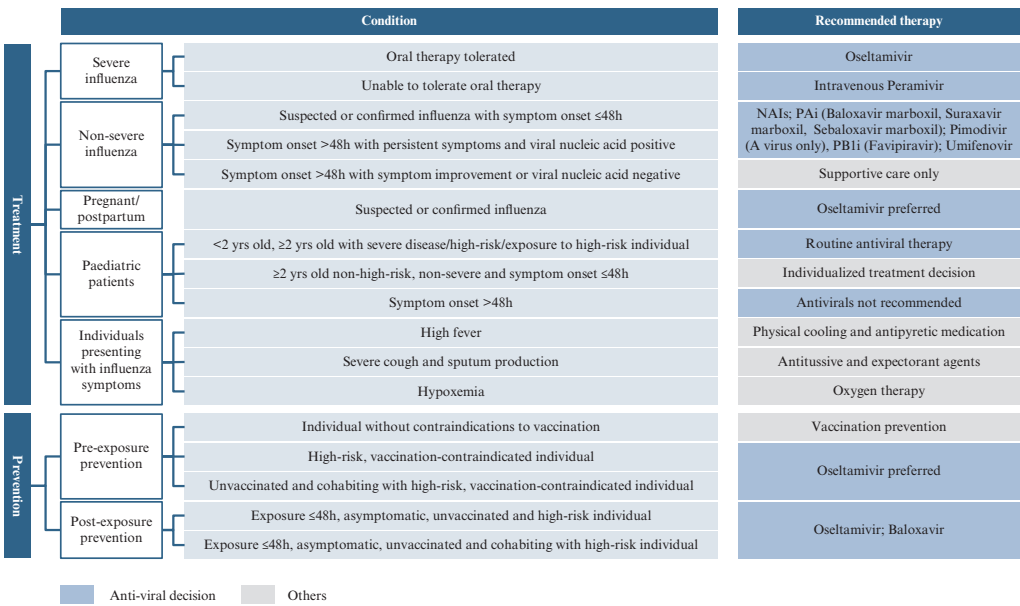
INDUSTRY OVERVIEW

Influenza exhibits seasonal circulation globally, with annual incidence significantly higher in children (20%–30%) than in adults (5%–10%). According to the World Health Organization (“WHO”), approximately 1 billion infections and up to 650,000 deaths occur worldwide each year, of which approximately three to five million are severe cases (0.3%–0.5%), implying that more than 99% of seasonal influenza cases are non-severe and generally fall within the clinical scope of uncomplicated influenza. In China, influenza prevalence shows marked seasonality and regional variation, with excess mortality rates in northern cities (12.4 per 100,000) higher than in southern cities (8.8 per 100,000). In the MENA, influenza exhibits weak seasonality and multi-peak circulation across temperate and Gulf countries, with an annual symptomatic incidence of approximately 10.2%. The elderly and children are identified as populations at high risk of severe infection.

Treatment Paradigms for Prevention and Treatment of Influenza

The management and prevention of influenza are typically stratified based on disease severity and seasonal risk. Clinical guidelines emphasize that during influenza seasons, antiviral therapy should be initiated as early as possible for ILI patients with risk factors for severe or critical disease. The greatest clinical benefit is achieved when antiviral medications are administered within 48 hours of symptom onset. The following schematic diagram illustrates the main diagnostic and therapeutic pathways following influenza infection.

Overview of Treatment Paradigm of Influenza in China



Source: Influenza Diagnosis and Treatment Guideline (2025 Edition); Diagnosis and Treatment Protocol for Influenza (2025 Edition, China); Clinical Practice Guidelines for the Treatment and Prophylaxis of Influenza in China (2025 Edition); CIC

Notes: 1. Antibiotics are not routinely indicated for influenza; use only if bacterial co-infection is suspected, with close monitoring and prompt pathogen testing; 2. Traditional Chinese medicine is applicable to all populations, with treatment tailored by disease severity and individualized according to time, location, and patient characteristics; 3. NAI, neuraminidase inhibitor; PAi, polymerase acidic (PA) inhibitor(s); CN, China

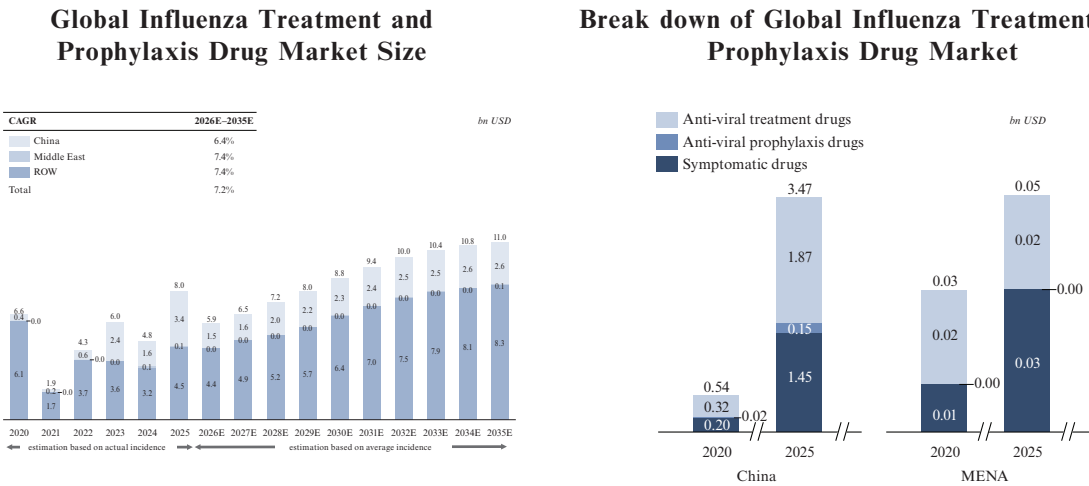
Sebaloxavir marboxil has demonstrated favorable efficacy and a good safety profile in clinical studies. As indicated in the Clinical practice guidelines for the treatment and prophylaxis of influenza in China (2025 edition), it is currently approved for adults and has shown favorable efficacy in non-severe, non-high-risk patients, significantly shortening the time to symptom relief with no notable adverse events.

INDUSTRY OVERVIEW

Unmet Needs for Influenza Treatment and Prophylaxis Drugs

Unmet needs for influenza treatment and prophylaxis drugs include: (i) Influenza vaccination uptake in China remains low. According to the Chinese Center for Disease Control and Prevention (“China CDC”), influenza vaccination coverage was only 3.84% during the 2022/2023 influenza season, with approximately 42.9 million doses administered during the 2024/2025 influenza season. Coupled with the moderate effectiveness of influenza vaccines, which typically ranges from approximately 40% to 60% depending on the season and circulating strains, vaccination alone remains insufficient to effectively control influenza transmission. (ii) Post-exposure chemoprophylaxis with NAIs demonstrates limited real-world effectiveness. (iii) In out-of-hospital settings, patients often forgo antiviral therapy, limiting both effective treatment and prevention of influenza. (iv) NAIs achieve slow viral clearance, with adherence and efficacy further compromised by adverse reactions. (v) Accessibility of PA inhibitors remains insufficient, as some indications in China, such as treatment for younger children and prevention for the general population, have not yet been fully approved.

Influenza Treatment and Prophylaxis Drug Market Size



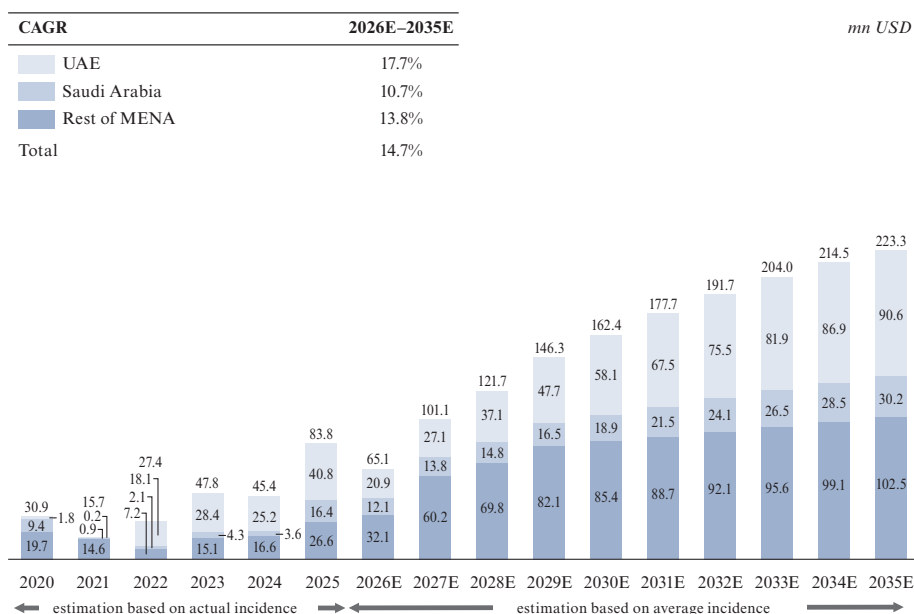
Source: the Lancet; Nature Communications; China CDC; U.S. CDC; CIC

Note: 1. MENA influenza treatment and prophylaxis drug market sizes from 2020 to 2035 are 0.03, 0.02, 0.03, 0.05, 0.05, 0.05, 0.03, 0.03, 0.03, 0.03, 0.03, 0.03, 0.04, 0.04, 0.05, and 0.05 USD bn, respectively; 2. The MENA antiviral prophylaxis drug market size is at USD0.001 bn in 2020 and USD0.002 bn in 2025.

The above chart shows the market size and breakdown of influenza drugs, including antiviral therapies (for both treatment and prophylaxis) and symptomatic treatments. The market size of influenza treatment and prophylaxis drugs represents the addressable market for uncomplicated seasonal influenza caused by influenza A and B viruses, excluding avian and other zoonotic influenza virus infections. The global influenza treatment and prophylaxis drug market is closely correlated with seasonal influenza activity and therefore exhibits year-to-year fluctuations. The relatively lower market size between 2020 and 2022 primarily reflected reduced influenza transmission during the COVID-19 pandemic due to widespread non-pharmaceutical interventions, including mask wearing, social distancing and travel restrictions. The increase in market size in 2023 reflected the resumption of seasonal influenza circulation following the relaxation of pandemic-related measures. The higher market size estimated for 2025 reflects updated epidemiological data from major markets. The U.S. Centers for Disease Control and Prevention estimated at least 11 million influenza illnesses in the 2025/26 season by early January 2026, compared with approximately 5.3 million during the corresponding period of the previous season. In addition, the World Health Organization reported elevated seasonal influenza activity across many countries.

INDUSTRY OVERVIEW

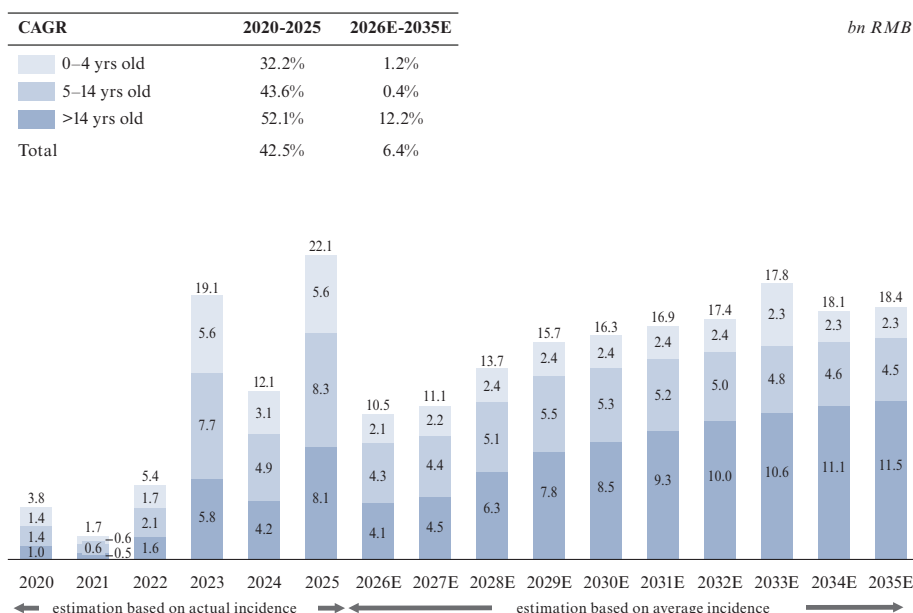
MENA Influenza Treatment and Prophylaxis Drug Market Size



Source: the Lancet; Nature Communications; WHO; World Bank; CIC

The above charts set forth the influenza drug market size in the MENA region, further segmented into key markets including Saudi Arabia and the United Arab Emirates.

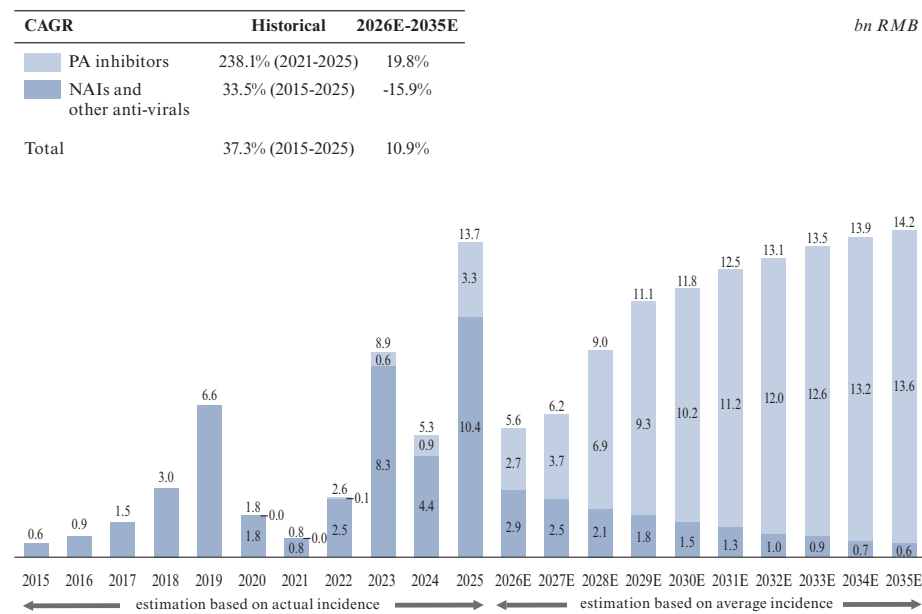
China Influenza Treatment and Prophylaxis Drug Market Size



Source: the Lancet; Nature Communications; China CDC; U.S. CDC; CIC

INDUSTRY OVERVIEW

China Influenza Anti-viral Treatment and Prophylaxis Drug Market Size



Source: the Lancet; Nature Communications; China CDC; CIC

The above two charts set forth the market size of influenza anti-viral treatment and prophylaxis drugs in China. Data for 2020 to 2025 reflect actual market estimates. The decline in 2021 was primarily attributable to reduced influenza transmission during the COVID-19 pandemic, followed by market recovery after the relaxation of pandemic-related measures. Confirmed influenza cases reported by sentinel surveillance hospitals increased by 266% year-on-year to 12.8 million in 2023 and by 100% year-on-year to 17.2 million in 2025, according to the China CDC. Projections from 2026 are based on historical average incidence rates. From 2028 onwards, market growth is expected to accelerate, driven by additional approved indications of influenza drugs.

Competitive Landscape of Influenza Antiviral Drug Market

Influenza antiviral drugs have undergone multiple generations of development, progressing from M2 ion channel inhibitors to NAIs. The latest generation, PA polymerase inhibitors, enable single-dose oral administration, achieve earlier viral clearance, and reduce the risk of transmission. They therefore offer advantages over previous drugs in terms of lower resistance rates, shorter treatment duration, higher adherence, and broader therapeutic coverage.

INDUSTRY OVERVIEW

Comparative Overview of Influenza Antiviral Drugs by Generations

Generation	Representative Drugs	Mechanism of Action	Dosing Regimen	Key Clinical Outcomes (Symptom Relief)	Key Clinical Outcomes (Virologic Outcomes)	Lineage Coverage	Guideline Recommendation
1st Generation: Adamantanes (amantadine class) .	Amantadine, Rimantadine	Inhibition of influenza A M2 ion channel	Multi-day oral regimen	Early studies suggested symptom reduction	NA (not active against influenza B)	Influenza A only	No longer recommended by U.S. CDC or Chinese guidelines
2nd Generation: Neuraminidase inhibitors (NAIs) . .	Oseltamivir, Zanamivir, Peramivir	Inhibition of neuraminidase, leading to blockade of progeny virion release	5-day regimen (oseltamivir); inhaled and IV formulations available	Median time to symptom relief: 53.8 h (oseltamivir) vs. 80.2 h (placebo)	Median time of viral shedding: 24.0h (baloxavir) vs 96.0h (placebo) vs 72.0h (oseltamivir)	Influenza A/B	First-line therapy for prevention and treatment of influenza, early intervention is recommended; recommended for high-risk populations or severe cases; recommended for post-exposure prophylaxis
3rd Generation: PA inhibitors	Baloxavir marboxil and others	Inhibition of the viral PA endonuclease, blocking viral mRNA synthesis and thereby preventing viral replication at its source	Single oral dose	Median time to symptom alleviation: 53.7 hours (baloxavir) vs 80.2 hours (placebo), with a reduction of 33.0%	Median time of viral shedding: 24.0h (baloxavir) vs 96.0h (placebo) vs 72.0h (oseltamivir)	Influenza A/B	First-line therapy for prevention and treatment of influenza, early intervention is recommended; recommended for high-risk populations; recommended for post-exposure prophylaxis

Source: US/CN CDC; NEJM; The Lancet; CAPSTONE-1 study; Clinical practice guidelines for the treatment and prophylaxis of influenza in China (2025 edition); CIC

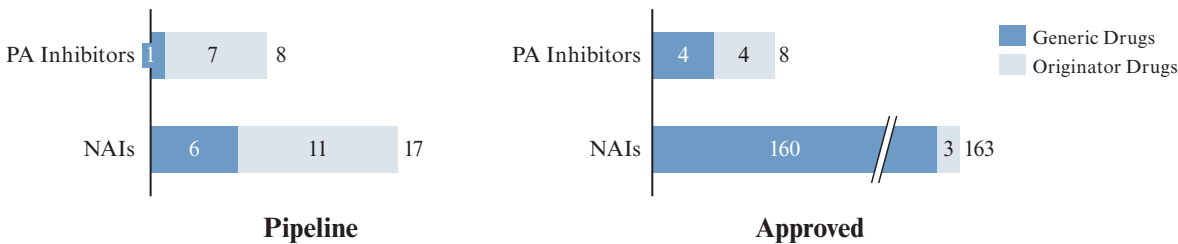
Compared with NAIs, which block viral release from infected cells, Sebaloxavir marboxil acts earlier in the influenza virus life cycle by inhibiting the PA endonuclease activity of the viral polymerase, potentially leading to more rapid reduction in viral replication and shorter symptom duration. Clinical studies indicate that Sebaloxavir marboxil demonstrates broad antiviral activity against influenza A and B strains and provides efficacy comparable to approved antiviral therapies. Although oseltamivir resistance has been observed in certain viral variants, and other PA endonuclease inhibitors have been associated with multidrug resistance-related substitutions at the PA I38 site, clinical data for Sebaloxavir marboxil suggest that resistance mutations are less frequent and more narrowly distributed.

As a single-dose oral antiviral, Sebaloxavir marboxil offers greater convenience and a favorable resistance profile compared with NAIs, as well as a longer half-life (83–126 h) compared with other PA inhibitors. Moreover, Sebaloxavir marboxil demonstrates a significant advantage in gastrointestinal safety, with low incidence of gastrointestinal adverse reactions, which is substantially lower than that reported for Baloxavir (3% diarrhea/2% nausea in adults, and the combined rate of vomiting and diarrhea was 10.4% in children). This may further improve patient compliance. On the other hand, clinical data in high-risk populations, including elderly individuals, immunocompromised patients, pregnant individuals, and hospitalized patients, remain limited.

INDUSTRY OVERVIEW

The following two charts provide an overview of approved and pipeline influenza antiviral drugs in China and globally, covering both originator and generic PA inhibitors and NAIs across all dosage forms.

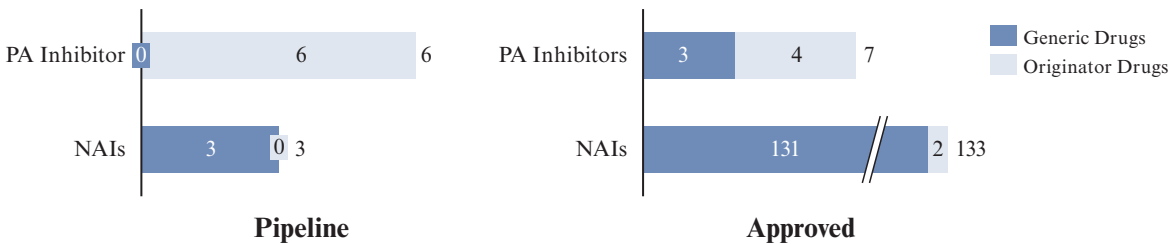
Global Overview of Originator and Generic PA Inhibitors and NAIs, as of the Latest Practicable Date



Source: ClinicalTrials; CIC

Note: The number of pipeline is calculated based on the number of products

Overview of Originator and Generic PA Inhibitors and NAIs in China, as of the Latest Practicable Date



Source: CDE, CIC

Note: Three PA inhibitors have passed the consistency evaluation of the quality and efficacy of generic drugs and obtained generic drugs approvals from NMPA, but have not yet been commercialized due to patent-related constraints.

The following tables set forth an overview of the approved originator influenza antiviral drugs in the world as of the Latest Practicable Date.

Global Competitive Landscape of Originator Influenza Antiviral Drugs, as of the Latest Practicable Date

Generic/Trade Name	MoA	Company	Initial Approval Date	Median Time to Symptom Alleviation	Elimination Half-life	Detailed Indication in China and U.S.		Treatment Cost in China (RMB)
						Treatment	Prophylaxis	
Baloxavir marboxil 速福達/ Xofluza . . .	PA inhibitor	Roche	Tablets: ● CN: 2021–4 ● US: 2018–10 Suspension: ● CN: 2023–12 ● US: 2020–11	53.7 h vs 80.2 h (33.0% reduction)	79.1 h	US: Acute, uncomplicated influenza in patients aged ≥5 years who have been symptomatic for ≤48 hours and who are otherwise healthy or at high risk of developing influenza-related complications. CN: Acute, uncomplicated influenza A or B in patients aged ≥5 years, including patients who are at high risk of influenza-related complications. CN (Suspension): Uncomplicated influenza A or B in pediatric patients aged 1 to <12 years, including otherwise healthy patients and those at high risk of influenza-related complications.	US: Post-exposure prophylaxis of influenza in patients aged ≥5 years following contact with an individual with influenza	Suspension: 193 Tablets: 222

INDUSTRY OVERVIEW

Generic/Trade Name	MoA	Company	Initial Approval Date	Median Time to Symptom Alleviation	Elimination Half-life	Detailed Indication in China and U.S.		Treatment Cost in China (RMB)
						Treatment	Prophylaxis	
Suraxavir marboxil 伊速達	PA inhibitor	QingFeng Pharmaceutical	● CN: 2025-03	42.0 h vs 63.0 h (33.3% reduction)	58.1 — 75.9 h	Uncomplicated influenza A and B infections in patients aged ≥12 years	Not approved	175
Sebaloxavir marboxil 濟可舒	PA inhibitor	Zenshine Pharmaceuticals	● CN: 2025-07	39.4 h vs 62.9 h (37.4% reduction)	83 — 126 h	Uncomplicated influenza A and B infections in patients aged ≥12 years	Not approved	222
Pixavir marboxil 壹立康	PA inhibitor	Joincare Pharmaceutical	● CN: 2025-12	60.9 h vs 87.9 h (30.7% reduction)	33.8 — 39.4 h	Uncomplicated influenza A and B infections in patients aged ≥12 years	Not approved	198
Favipiravir 海復康	PB1 inhibitor	Hisun Pharmaceutical	● CN: 2020-02	84.2 h vs 98.6 h (14.6% reduction)	2.5 — 5 h	Novel or re-emerging influenza in adults, for use when other anti-influenza antiviral drugs are ineffective or insufficient	Not approved	N/A
Onradivir 安睿威	PB2 inhibitor	Zhongsheng Pharma	● CN: 2025-05	38.8h vs 63.4h (38.8% reduction)	12 — 35 h	Uncomplicated influenza A infections in adults	Not approved	N/A
Oseltamivir phosphate 達菲/Tamiflu	NAI	Roche	Capsule: ● CN: 2001-01 ● US: 1999-10 Suspension: ● US: 2000-12	53.8 h vs 80.2 h (32.9% reduction)	6 — 10 h	US: Acute, uncomplicated influenza A and B in patients aged ≥2 weeks who have been symptomatic for no more than 48 hours CN: Acute, uncomplicated influenza A and B in patients aged ≥1 year who have been symptomatic for no more than 48 hours	US: Prophylaxis of influenza A and B in patients aged ≥1 year CN: Prophylaxis of influenza A and B in adults and adolescents aged ≥ 13 years	Capsule: 172
Zanamivir 依樂韋/Relenza	NAI	GSK	● US: 1999-07 ● CN: 2009-07	120 h vs. 144 h (16.7% reduction)	2.5 — 5.1 h	US: Treatment of uncomplicated acute influenza A/B in patients aged ≥7 years who have been symptomatic for ≤48 h. CN: Treatment of influenza A/B in adults and children aged ≥7 years; treatment should be initiated within 48 hours	US: Prophylaxis of influenza in patients aged ≥5 years	N/A
Peramivir 瑞貝塔/Rapivab	NAI	BioCryst	● US: 2014-12	59.1 h (300 mg)/ 59.9 h (600 mg) vs. 81.8 h (27.8%/26.8% reduction)	20 h	US: Acute uncomplicated influenza in patients aged ≥6 months who have been symptomatic for ≤2 days	Not approved	N/A

Source: Public Information; Annual Reports; the Lancet; NEJM; CIC

Notes: 1. Only showing originator drugs; 2. Median time to symptom alleviation refers to the median time to symptom relief in the treatment group compared with that in the placebo group; 3. Treatment cost (excluding the suspension) is calculated based on an adult body weight of 75 kg, whereas the suspension treatment cost is calculated based on an average body weight of 28.75 kg for boys and girls aged 5–11 years, according to the 2014 National Physical Fitness Monitoring Bulletin; 4. “Uncomplicated influenza” refers to influenza infection without severe manifestations, complications, or high-risk comorbidities, typically presenting with fever, respiratory symptoms, and malaise but without pneumonia, hospitalization, or organ dysfunction, and this definition aligns with internationally recognised guidance from WHO, FDA, and the Clinical Practice Guidelines for the Treatment and Prophylaxis of Influenza in China(2025 edition); 5. These data have not been evaluated in head-to-head trials.; 6. EUA = Emergency Use Authorization; 7. Baloxavir marboxil (tablets), Suraxavir marboxil, Favipiravir, Onradivir, and Oseltamivir (conventional oral dosage forms, granules, and powder for suspension), as well as domestic generic injectable formulations of Peramivir, are covered by the NRDL, while Sebaloxavir marboxil, Pixavir marboxil, and Zanamivir are not covered; 8. N/A refers to not available; 9. Peramivir (Rapivab) developed by BioCryst Pharmaceuticals has not been approved in PRC. Peramivir modified formulation was approved in mainland China, with Guangzhou Nanshin Pharmaceutical Co., Ltd. as the originator; 10. Tamiflu (branded oseltamivir capsule): RMB172/course (based on pre-VBP branded price)

Kewei is a generic oseltamivir phosphate granule product and the best-selling NAIs in Chinese Mainland in 2025. It is indicated for the treatment of influenza A and B in children aged 2 weeks and older and in adults, or for the prophylaxis of influenza A and B in patients aged 1 year and older. Based on an average body weight, the complete treatment cost of Kewei is RMB163.96 for children and 204.95 for adults as of the Latest Practicable Date.

INDUSTRY OVERVIEW

In China, most anti-influenza antiviral drugs are included in the National Reimbursement Drug List (“NRDL”), such as Oseltamivir and Baloxavir marboxil (“速福達”), improving patient affordability and access through public medical insurance coverage. Sebaloxavir marboxil (“濟可舒”) and Pixavir marboxil (“壹立康”) were launched recently and have not yet been included in the NRDL price negotiation process. As of the Latest Practicable Date, PA inhibitors have not been incorporated into national volume-based procurement (“VBP”) programs, whereas NAIs have been included in both national and provincial centralized procurement initiatives, significantly reducing drug prices. VBP has been applied to oseltamivir products in China, with different winning bid prices across dosage forms. In the seventh national VBP round in 2022 covering oseltamivir capsules, the lowest winning bid price was approximately RMB0.99 per capsule (30 capsules per box) offered by Dongyangguang Pharmaceutical, while other winning bid prices for generic oseltamivir capsules were generally approximately RMB1.5–2.7 per capsule. In the eleventh national VBP round in 2025 covering oseltamivir phosphate granules, the lowest winning bid price was approximately RMB17.88 per box (900 mg specification); however, this product was not ranked among the top 20 oseltamivir products by sales volume in China. Kewei, the leading oseltamivir product by sales value, did not participate in VBP and maintained its leading market position.

INDUSTRY OVERVIEW

The following tables set forth an overview of the development stage influenza PA inhibitors in the U.S. and China, as of the Latest Practicable Date.

Pipeline of Influenza PA Inhibitors in China, as of the Latest Practicable Date

Drug Name	Company	Dosage Form	Indication	Phase
Deunoxavir Marboxil (ADC189)	Jiaxing AnDiCon Biotech	Tablets	Patients aged ≥ 5 years with acute influenza A or B Adults and adolescents with uncomplicated influenza A or B	NDA
		Granules	Children aged ≥ 2 years and adults with uncomplicated influenza A or B Post-exposure prophylaxis against influenza A and B for individuals aged ≥ 2 years	Phase 3
Suraxavir marboxil (GP681).	Jiangxi Kerui Pharmaceutical Jiangxi Kerui Pharmaceutical	Suspension	Children aged 2 years to < 12 years with uncomplicated influenza A or B	
		Tablets	Post-exposure prophylaxis of influenza in adults and adolescents aged 12 years and older Adults and adolescents aged 12 years and older with influenza who are at high risk for influenza-related complications	NDA
Seloxavir Marboxil (ZX-7101A)	Zenshine Pharmaceuticals	Suspension	Children aged 2–11 years with uncomplicated influenza	NDA
		Tablets/ Suspension	Post-exposure prophylaxis against influenza in household contacts aged ≥ 2 years	Phase 3
TG-1000/JKN2301	Joicare Haibin Pharmaceutical Joicare Pharmaceutical Group Industry	Suspension	Children aged 2 weeks to < 12 years with uncomplicated influenza A or B	Phase 3
102D-6	Cavendish (Taizhou) Pharmaceutical	Suspension	Patients aged ≥ 5 years with uncomplicated influenza A and B	Phase 2
SYH2085	CSPC Zhongqi Pharmaceutical Technology Shijiazhuang	Tablets	Patients aged ≥ 12 years with uncomplicated influenza A and B	Phase 1

Source: CDE; CIC

Note: 1. List only active pipeline of novel drugs, not including those whose study status is “unknown”, “completed”, “terminated”, “withdrawn” and “suspended”

Pipeline of Influenza PA Inhibitors in the U.S., as of the Latest Practicable Date

Drug Name	MoA	Administration	Indication	Company	Phase
Baloxavir Marboxil . .	PA inhibitor	Oral	Influenza in Pediatric Patients	Roche	Phase 3

Source: ClinicalTrials; CIC

Note: 1. List only active pipeline of novel drugs, not including those whose study status is “unknown”, “completed”, “terminated”, “withdrawn” and “suspended”

INDUSTRY OVERVIEW

As of the Latest Practicable Date, three generic PA inhibitors had obtained marketing approvals from the NMPA, but had not been commercialized as the relevant compound patents remain in force and restrict their commercial launch before patent expiry. The approved indications of such generic drugs are subject to their respective NMPA approvals and do not automatically extend to additional indications of the originator drug. Such patent protection is not expected to affect the indication expansion or commercialization of sebaloxavir marboxil, which is supported by its own clinical development program and regulatory pathway. The primary generic pressure is expected to come from the potential future market entry of generic PA inhibitors (Baloxavir marboxil after 2036 and Sebaloxavir marboxil after 2040). However, leveraging first-mover advantages and accumulated clinical data, Sebaloxavir marboxil is likely to maintain a stronger market positioning relative to generics. In clinical practice, physicians tend to prefer drugs that are supported by robust clinical data. Furthermore, drawing on the performance of Oseltamivir phosphate in the NAIs market, the originator drug continues to retain a sufficiently stable market share.

Future Trends and Growth Drivers of the Influenza Antiviral Drug Market

Future trends and growth drivers of the influenza antiviral drug market include: (i) PA polymerase inhibitors are expected to increase the rate of antiviral treatment outside hospital settings. (ii) Increasing use for post-exposure prophylaxis as next-generation agents better suit preventive settings. (iii) Increasing public awareness of antiviral-based management is driving demand expansion. (iv) Vaccination gaps create persistent demand for antiviral therapies. (v) Regulatory reforms and investment in antiviral R&D support broader market penetration.

OVERVIEW OF ENPP1 INHIBITOR MARKET

Overview of ENPP1-Targeted Oncology Drug Market

Ectonucleotide pyrophosphatase/phosphodiesterase 1 (“ENPP1”), as an extracellular hydrolase, disrupts immune signaling by degrading cGAMP and promotes an immunosuppressive tumor microenvironment. It is highly expressed in multiple solid tumors, including hepatocellular carcinoma, ovarian cancer, pancreatic cancer, and triple-negative breast cancer, and is closely associated with poor prognosis and immune evasion. Inhibition of ENPP1 restores STING activation, enhances antitumor immune responses induced by DNA-damaging therapies, and holds promise for converting “cold” tumors into immunologically responsive tumors.

Competitive Landscape of ENPP1-Targeted Oncology Drug Market

Global Pipeline of ENPP1-Targeted Oncology Drugs, as of the Latest Practicable Date

Drug Name	Company	Indication	Therapy Type	Location	Phase
SR-8541A . .	Stingray Therapeutics	Refractory Metastatic Microsatellite Stable Colorectal Cancer	Combo with ICI (Botensilimab and Balstilimab)	U.S.	Phase 2
		Advanced Unresectable Hepatocellular Carcinoma	Combo with ICI (STRIDE regimen: Durvalumab + Tremelimumab)	U.S.	Phase 2
RBS2418 . . .	Riboscience, LLC.	Metastatic Colorectal Cancer; Advanced Colorectal Cancer	Monotherapy + Best Supportive Care	U.S. and others	Phase 2
		Advanced Unresectable, Recurrent or Metastatic Tumors	Monotherapy; Combo with ICI (Pembrolizumab)	U.S.	Phase 1
TXN10128 . .	Txinno Bioscience Inc.	Locally Advanced (Unresectable) or Metastatic Solid Tumors	Monotherapy; Combo with Chemotherapy (Irinotecan or Paclitaxel)	South Korea	Phase 1
ISM5939 . . .	Insilico Medicine Hong Kong Limited	Advanced and/or Metastatic Solid Tumors	Monotherapy; Combo with Chemotherapy (Cisplatin or Docetaxel); Combo with ICI (Pembrolizumab)	N/A	Phase 1
ZX-8177 . . .	Our Company	Advanced Solid Tumors	Monotherapy	China	Phase 1

Source: ClinicalTrials; CDE; CIC

INDUSTRY OVERVIEW

Notes: 1. List only active pipeline of novel drugs, not including those whose study status is “unknown”, “completed”, “terminated”, “withdrawn” and “suspended”; 2. “Others” under Location represents multinational clinical studies conducted in countries and regions other than the U.S.

It is estimated that by 2035, the global market size of ENPP1-targeted immuno-oncology therapies will reach approximately USD524 million.

Overview of HPP Treatment Market

Hypophosphatasia (“HPP”) is a rare inherited metabolic disorder caused by ALPL mutations and defective bone mineralization. Pediatric-onset HPP is generally more severe, with skeletal abnormalities and potentially life-threatening complications, while adult-onset HPP is typically milder, with fractures, musculoskeletal pain and impaired mobility. Strensiq® (asfotase alfa), an enzyme replacement therapy for perinatal-, infantile- and juvenile-onset HPP, is currently the only drug approved globally for HPP and has not been approved in mainland China. Annual treatment cost of Strensiq in the U.S. can exceed US\$1 million per patient, depending on body weight. For patients not receiving enzyme replacement therapy, particularly those with milder or adult-onset disease, current management is largely supportive and symptomatic, such as fracture and pain management. ENPP1 inhibitor reduce the production of extracellular inorganic pyrophosphate, a key inhibitor of mineralization, thereby promoting bone mineralization through a mechanism distinct from enzyme replacement therapy. ENPP1 inhibition represents a potential therapeutic approach for HPP across different ages of onset and disease severities, including both pediatric- and adult-onset HPP.

Competitive Landscape of HPP Treatment Drug Market

Global Pipeline of HPP Treatment Drugs, as of the Latest Practicable Date

Drug Name	Company	Indication	Therapy Type	Location	Phase
ALE1	Alesta Therapeutics	HPP in adults HPP in pediatric patients aged 2 to <12 years previously treated with asfotase alfa	Monotherapy Monotherapy; Active-controlled vs. Asfotase Alfa	Others U.S. and others	Phase 1/2 Phase 3
ALXN1850 . . .	Alexion Pharmaceuticals	HPP in treatment-naïve pediatric patients aged 2 to <12 years HPP in treatment-naïve adolescent and adult patients aged ≥12 years	Monotherapy Monotherapy	U.S. and others U.S. and others	Phase 3 Phase 3

Source: ClinicalTrials; CDE; CIC; Company Information

Notes: 1. List only active pipeline of innovative drugs, not including those whose study status is “unknown”, “completed”, “terminated”, “withdrawn” and “suspended”; 2. “Others” under Location represents multinational clinical studies conducted in countries and regions other than the U.S.; 3. Exclude symptomatic or supportive treatment pipeline

INDUSTRY OVERVIEW

Global Competitive Landscape of HPP Treatment Drugs, as of the Latest Practicable Date

Generic/Trade Name	MoA	Company	Initial Approval Date	Detailed Indication	Key Safety Data	Dosing Regimen
Asfotase alfa (Strensiq®)	Tissue-nonspecific alkaline phosphatase (TNSALP) enzyme replacement therapy; replacement of deficient TNSALP reduces inorganic pyrophosphate (PPi) accumulation and improves bone mineralization	Alexion Pharmaceuticals/ AstraZeneca	<ul style="list-style-type: none"> ● JP: 2015-07 ● EU: 2015-08 ● U.S.: 2015-10 	U.S.: Treatment of patients with perinatal/ infantile- and juvenile-onset HPP	Most common AEs: injection-site reactions (63%), lipodystrophy (28%), ectopic calcifications (14%), and hypersensitivity reactions (12%)	SC injection; 6 mg/kg/week: 2 mg/kg 3 × weekly or 1 mg/kg 6 × weekly; for perinatal/ infantile-onset HPP, may increase to 9 mg/kg/week (3 mg/kg 3 × weekly) for lack of efficacy

Source: ClinicalTrials; CIC; Company Information

OVERVIEW OF THE MARKET FOR HPV TREATMENT DRUGS

Overview of HPV Infection

HPV is a non-enveloped, double-stranded DNA virus that is highly prevalent in humans. Infection is broadly classified into high-risk types associated with genital tract cancers and other malignant lesions, and low-risk types that primarily cause warts and benign epithelial proliferations. The virus invades basal keratinocytes through disrupted epithelium and establishes long-term latent infection; most infections clear spontaneously within 1–2 years, while a small proportion of persistent infections may progress to malignancy.

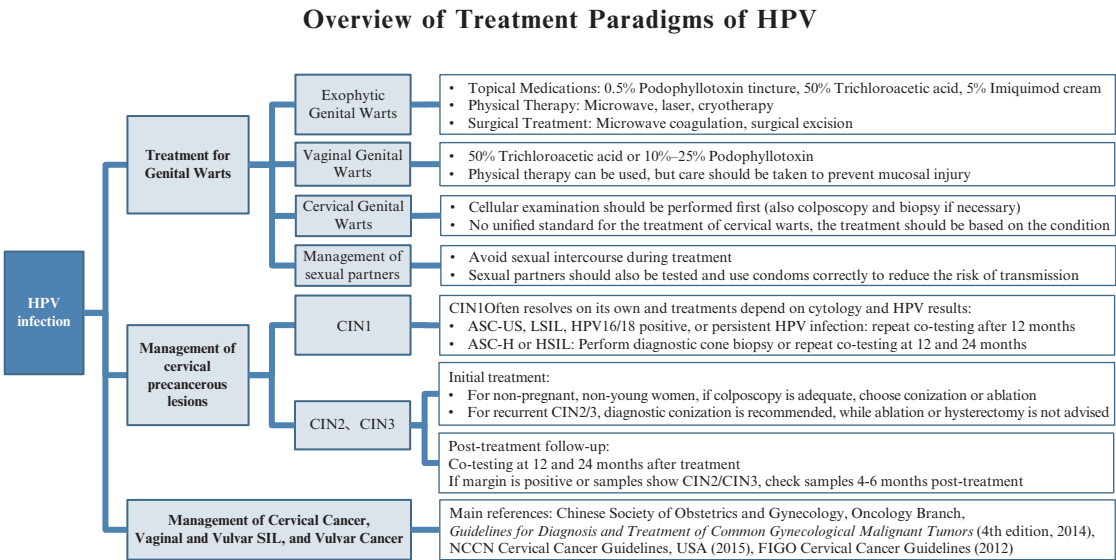
Epidemiology of HPV Infection

According to the Guideline for the Diagnosis and Treatment of Cutaneous Warts (2022) and largescale epidemiological data from China and the United States, the overall prevalence of viral warts in the general population is approximately 7%-12%, and 50%-80% of sexually active individuals may carry HPV; among Chinese women, approximately 120 million are infected with HPV (13.12% highrisk types and 4.58% lowrisk types), while in the United States, more than 42 million people are infected with types of HPV that are known to cause disease, with about 13 million new infections occurring annually.

INDUSTRY OVERVIEW

Treatment Paradigms for HPV Infection

The following diagram illustrates the major treatment pathways for HPV-related diseases in China.



Source: Expert Consensus on the Diagnosis and Treatment of HPV Infection of the Female Lower Genital Tract; CIC

Condyloma Acuminatum and Cervical Intraepithelial Lesions

Condyloma acuminatum, also known as anogenital warts, is a sexually transmitted disease caused by HPV infection and characterized by verrucous proliferative lesions of the skin and mucosa. Approximately 90%-95% of condyloma acuminatum cases are caused by low-risk HPV types 6 and 11. Anogenital HPV infection is common; based on cervical cytology samples, the adjusted prevalence of HPV infection in the cytologically normal global population is estimated at 11.7%. Most infections present as subclinical or latent infections.

Cervical intraepithelial lesions include low-grade squamous intraepithelial lesions (“LSIL”), corresponding to CIN 1, and high-grade squamous intraepithelial lesions (“HSIL”), which include CIN 2 and CIN 3.

Competitive Landscape of Anti-HPV Drug Market

INDUSTRY OVERVIEW

Global Pipeline of Anti-HPV Drugs, as of the Latest Practicable Date

Drug Name	Indication	Company	Region	Phase
DARE-HPV (Lopinavir/ Ritonavir)	Persistent high-risk HPV genital infection	Daré Bioscience	U.S.	Phase 2
Chloroquine Phosphate Gel	Women aged 18–50 years with high-risk HPV infection	Guangzhou HybriBio Biotech	China	Phase 2
ABI-2280.	Female, diagnosed with persistent cervical hrHPV infection	Frantz Viral Therapeutics	Australia, New Zealand	Phase 1/2
Monoterpenoid zinc tetra-ascorbo- camphorate (C14)	Female, diagnosed with persistent cervical hrHPV infection, low-grade dysplastic lesions of the cervix	MGB Biopharma	Democratic Republic of the Congo	Phase 1/2

Source: ClinicalTrials; CDE; CIC

Notes: 1. List only active pipeline of novel drugs, not including those whose study status is “unknown”, “completed”, “terminated”, “withdrawn” and “suspended”; 2. All candidates shown are originator drugs

Unmet Needs for Anti-HPV Drugs

(i) No therapy has been approved or has been definitively shown to “clear” or eradicate HPV infection. (ii) For non-high-risk HPV subtypes, effective preventive measures remain limited, and patient demand for achieving viral negativity is substantial. (iii) Current treatment approaches are unable to simultaneously achieve both viral clearance (HPV negativity) and repair of HPV-induced lesions, and recurrence remains common.

Future Trends and Growth Drivers of anti-HPV Drugs

(i) China’s large high-risk population drives dual demand for prevention and treatment. (ii) Advances in diagnostic technologies improve screening and detection rates, supporting growth in the therapeutic market. (iii) Commercialization of innovative therapies addresses treatment gaps and improves overall treatment rates.

REPORT COMMISSIONED BY CHINA INSIGHTS INDUSTRY CONSULTANCY LIMITED

In connection with the [REDACTED], we have engaged China Insights Industry Consultancy Limited (“CIC”) to conduct a detailed analysis and to prepare an industry report on the major markets for which our drugs candidates are positioned. CIC is an independent global market research and consulting company founded in 2014 and is based in China. We have agreed to pay CIC a total fee of approximately RMB1.0 million for the preparation of the CIC Report, and we believe that such fee is consistent with the market rate. The payment of such amount was not contingent upon our successful [REDACTED] or on the content of the CIC Report. Except for the CIC Report, we did not commission any other industry report in connection with the [REDACTED]. The market projections in the CIC Report were based on the following key assumptions: (i) the overall social, economic and political environment globally and in China is expected to remain stable during the forecast period; (ii) the economic and industrial development globally and in China is likely to maintain a steady growth trend over the next decade; (iii) related key industry drivers are likely to continue driving the growth of the market during the forecast period; and (iv) there is no extreme force majeure or industry regulation in which the market may be affected dramatically or fundamentally. The reliability of the CIC Report may be affected by the accuracy of the foregoing key assumptions, including those used to make future projections.