

# EV71 Vaccine Development





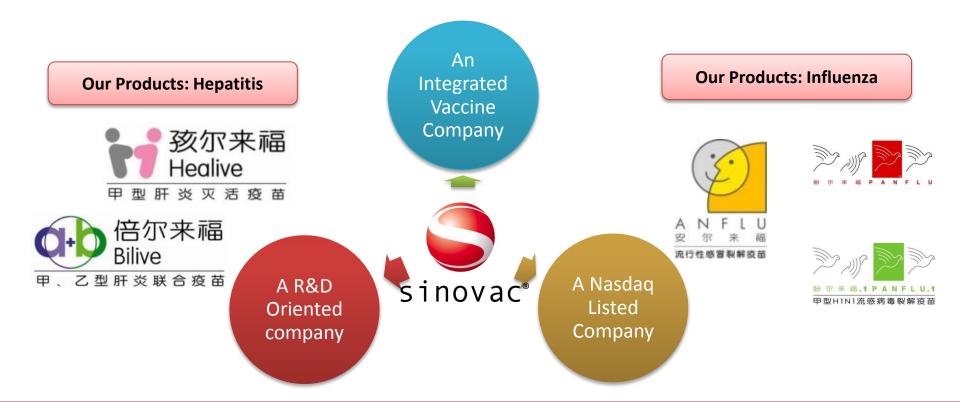


Weining Meng

DCVMN 15<sup>th</sup> Annual General Meeting

29th October, 2014

## Sinovac-A leading vaccine company in China



#### We are:

- 1<sup>st</sup> company to develop inactivated hepatitis A vaccine in China
- 1st company to develop combined hepatitis A and B vaccine in China
- 1st company to complete phase I clinical trial on SARS vaccine worldwide
- 1st company to develop H5N1 vaccine in China
- 1<sup>st</sup> company to develop and get license of H1N1 vaccine worldwide
- 1st and only Chinese vaccine company listed in Nasdaq

### **Our Mission**

### **Supply Vaccines To Eliminate Human Diseases**

- Provide Chinese Population with International Quality Vaccines
- Provide Vaccines Made in China to Worldwide

### **Our Products: Hepatitis**





#### Our Products: Influenza









## **Manufacturing Facilities**

### Manufacturing Plants

#### **Headquarter-Beijing**











Novel Vaccine Production Base

Capacity of Filling and Packaging: 100 million

Capacity of EV71: 10-20 million

Building Area: 29,000 square meters

#### **Dalian**

Vero Cell Cultured Vaccine and Live
Attenuated Vaccine



Tangshan

Yi'an Animal Vaccine



## **Hand Foot Mouth Disease Epidemic**

US, EV71 was isolated 1957 1969 1975 Taiwan, 80677 cases, 41 deaths 1997 1998 2000

2007

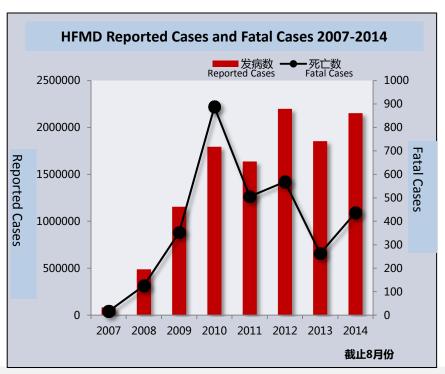
New Zealand,
Hand Foot Mouth
Disease was
reported and
defined

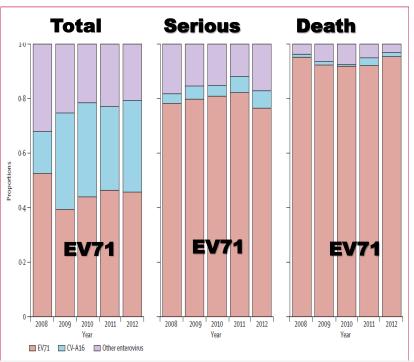
Bulgaria, 705 cases, 44 deaths

Malaysia, Taiwan, 2628 129106 cases, 30 cases, 78 deaths deaths Mainland of China, Korea, Viet Nan, etc. millions cases reported and thousands dead



## **EV71 Epidemic In China**





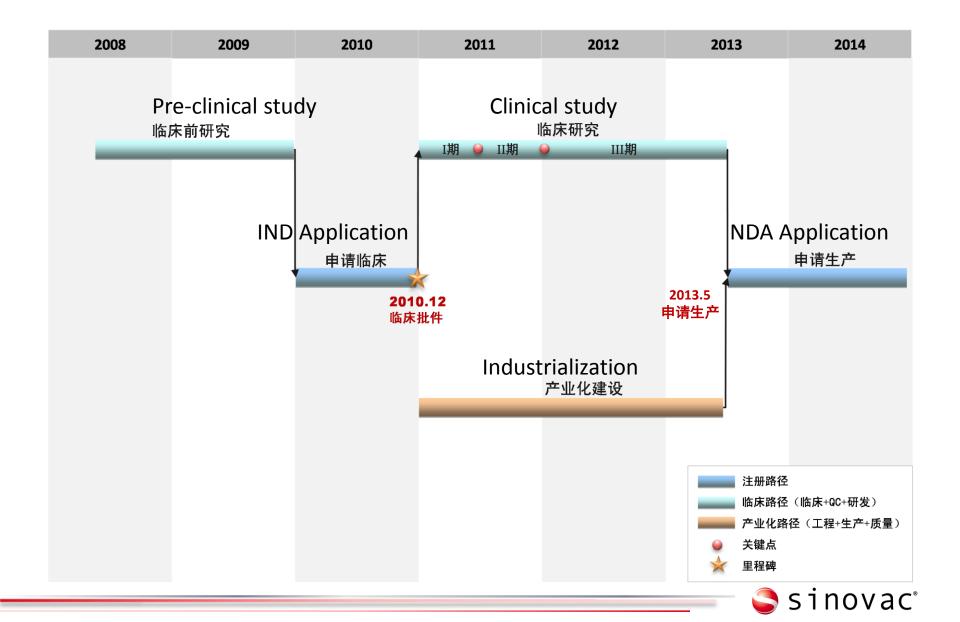
Serious HFMD epidemic in China;

**EV71** inducing main serious and fatal cases;

Vaccine against EV71 is the answer.



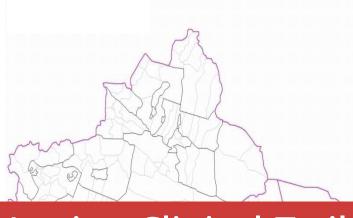
## **Development Milestones**



### **Characters of Sinovac EV71 Vaccine**

- ✓ Vero Cell, cell factory cultivation technology;
- √ H07 strain, C4 subgenotype, isolated by China CDC;
- ✓ Inactivation with formaldehyde
- √ Al(OH)3 as adjuvant
- √ 100 u/200u/400 u, 2 doses/3 doses regimen





## **EV71 Vaccine Clinical Trails**

#### Phase I

- Objective: Safety, Immunogenicity
- Subjects:
   Babies, children,
   and Adult
- Dose: 100U \\ 200U \\ 400U

168 subjects

#### Phase II

- Objective: Immunogenicity, safety
- Subjects: 6-35 months babies
- Dose: 100U \\ 200U \\ 400U

540 subjects

#### Phase III

- Objective:
   Protective
   effective
- Subjects: 6-35 months babies
- Dose: 400U

#### **Phase III**

- Objective: consistency
- Subjective: 6 months-5 years children
- Dose: 400U

10077 subjects

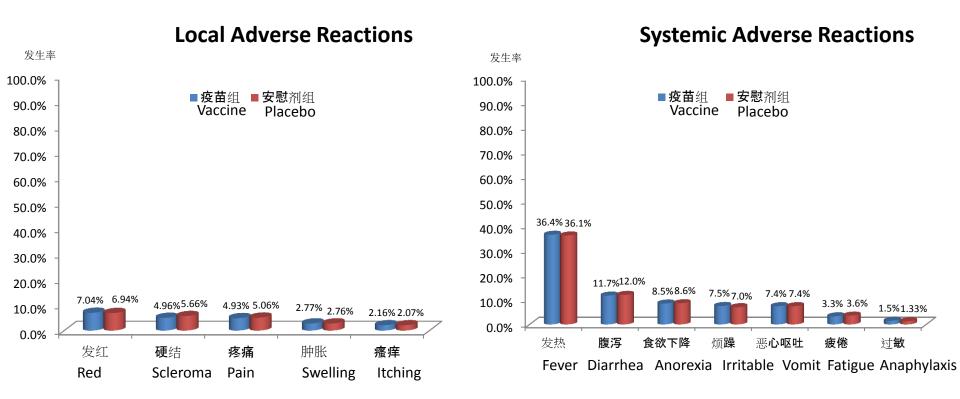
江苏

1400 subject s

All trials following GCP

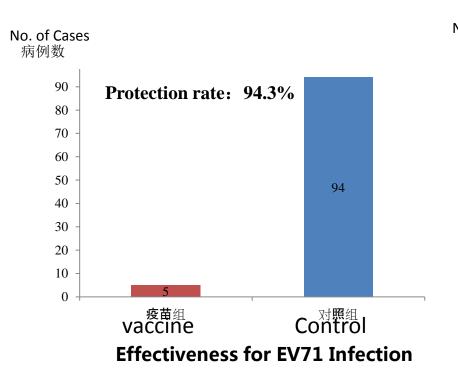
inovac®

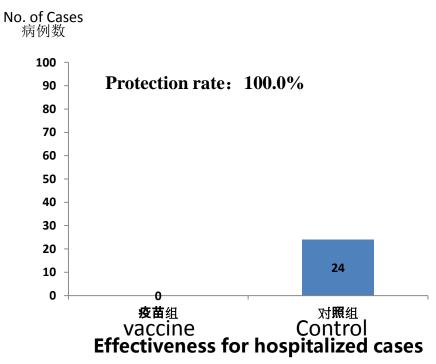
## **EV71 Vaccine-Safety**



No significant difference between vaccine group and placebo group

## **EV71 Vaccine-Efficacy**

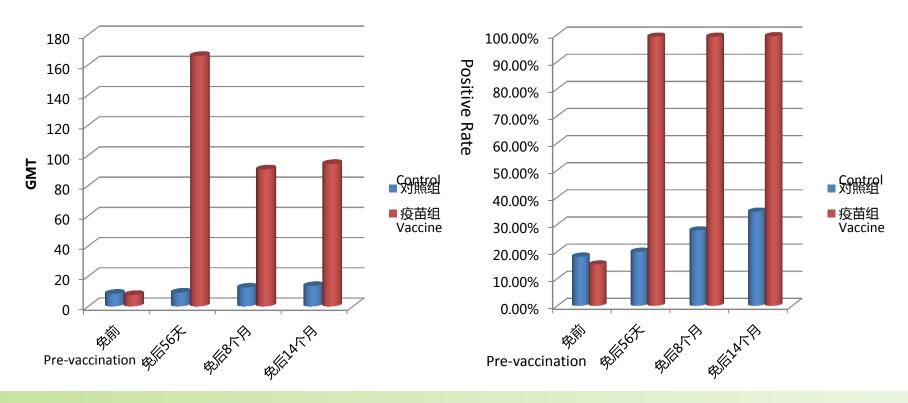




Protection rate for EV71 infection: 94.3%

Protection for hospitalized cases and serious cases: 100.0%

## **EV71 Vaccine-Immunogenicity**



56 days after vaccination, Neutralizing antibody positive rate 98.79%, GMT 165.79,
8 months and 14 months after vaccination, high level of antibody
Good immunogenicity and immune persistence.

### Industrialization

Total : 29,021 m<sup>2</sup>

Built-up area : 32,322  $\,\mathrm{m}^2$ 

### **Production**

19000 m<sup>2</sup>

Ready for use 4F QC Labs 3F **EV71** Bulk 20 million does/year **Formulation** 2F Filling & Packaging 100 million doses/year **Cold Room** 1F 1.8 million vials **Utilities** 

### **Others**

4000 m<sup>2</sup>

**2F** Animal Lab

**1F** Biobank

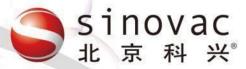
Office

9000 m2



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Supply vaccines to eliminate human diseases









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中国儿童使用国际水平的疫苗世界儿童使用中国生产的疫苗

Provide Chinese children with international quality vaccines

Provide children in the world with vaccines made in China