Infant Bacterial Therapeutics

Corporate Presentation
March 2018

INFANT BACTERIAL THERAPEUTICS

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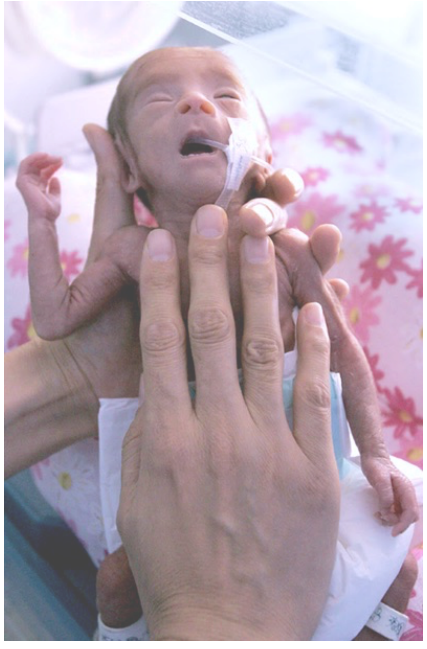
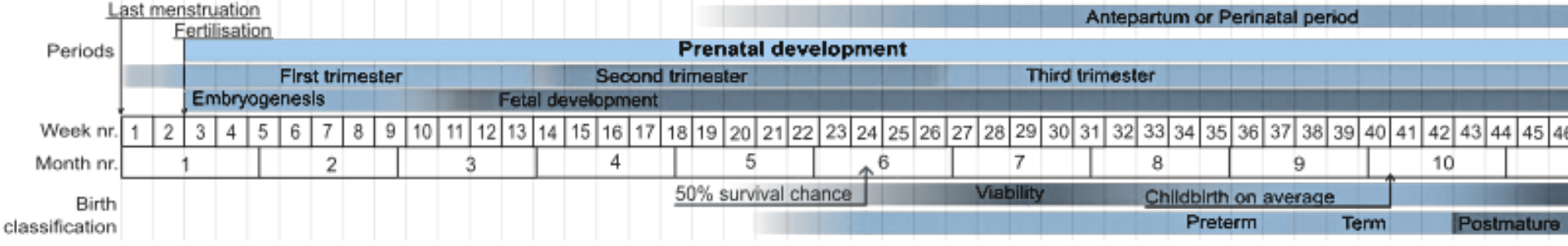
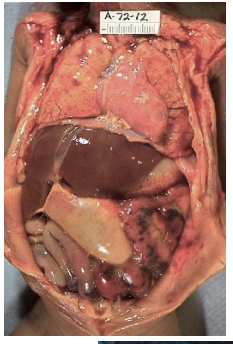
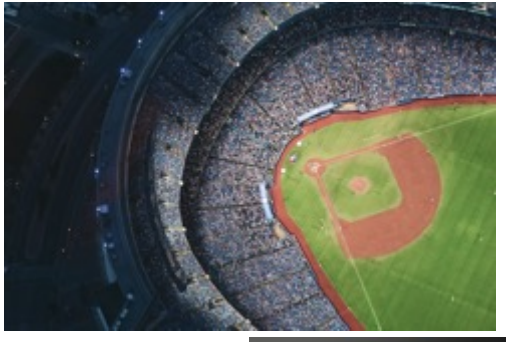



Last menstruation
Fertilisation
Periods
Antepartum or Perinatal period
Prenatal development
First trimester
Second trimester
Third trimester
Embryogenesis
Fetal development
Week nr.
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45
Month nr.
1 2 3 4 5 6 7 8 9 10
50% survival chance
Viability
Childbirth on average
Birth classification
Preterm
Term
Postmature

Lead drug candidate IBP-9414, to prophylactically prevent necrotizing enterocolitis (“NEC”), a fatal, rare disease that afflicts premature infants



Label Patient Population 56,000 children in US estimated up to USD 350m per year in US market for IBP-9414



Market Approval for IBP-9414 target 2020 / 2021 and grant of priority review voucher

The IBT concept

- IBT focuses on concepts of altering the human microbiome to prevent or treat diseases
- Microbiome of the newborn infant is more dynamic than that of the mature human
- Utilize co-evolved human bacterial strains derived from human breast milk
- Clinical proof-of-concept signal published to engage IBT in development

Picture designed by onlyyouqj / Freepik

Necrotizing Enterocolitis

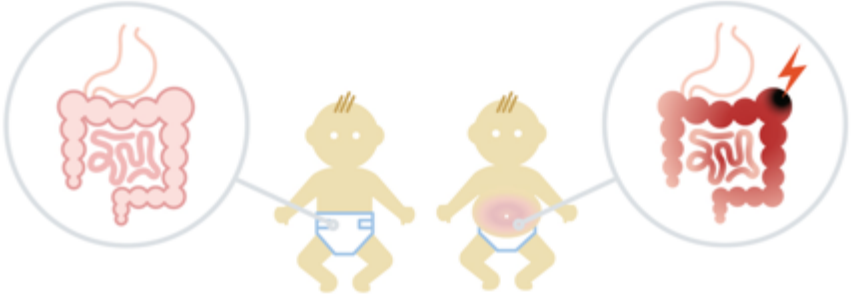
NEC is a severe inflammation and necrosis of the preterm infant bowel

True unmet medical need

- There is no therapy available today
- 20-40% need complicated and costly surgery
- One of the leading causes of death in NICU
- Up to 40% death rate, 1500 US and 3700 EU infants lost every year

Source Simpson 2010, Clark 2012

Who gets NEC?



	Infants birth weight	NEC incidence rate (%)	NEC mortality rate (%)	Mortality (% of weight cohort)
High incidence and mortality	501-750g	12.0%	42.0%	5.0%
	751-1,000g	9.2%	29.4%	2.7%
	1,001-1250g	5.7%	21.3%	1.2%
	1,251-1,500g	3.3%	15.9%	0.5%
	1,501-2,500g	0.4%	8.2-17%	0.03-0.06%
	>2,500g	0.1%	0-20%	0-0.02%

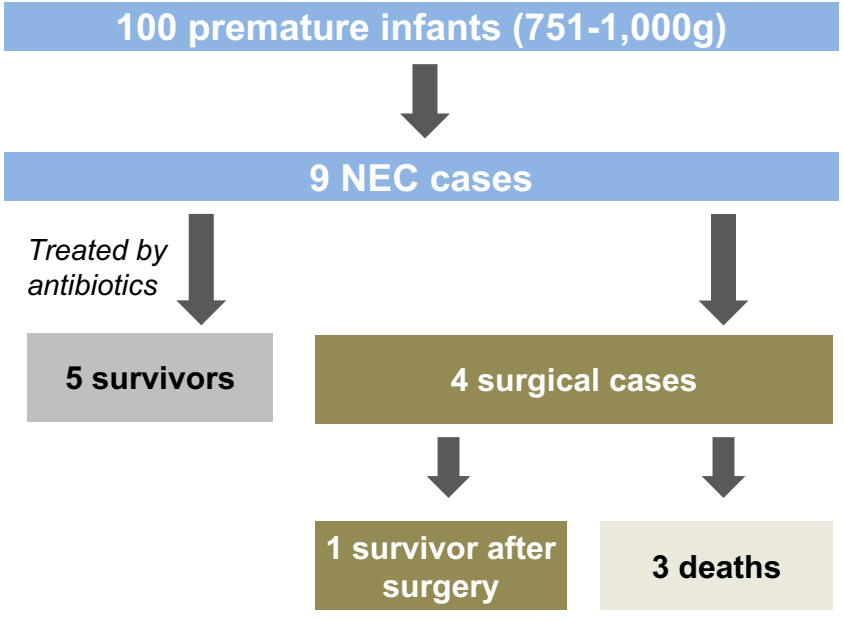
The smaller the premature infant is at birth, the more likely he/she will get NEC and die.

Source Shelley 2012, Bolisetty 2000, Llanos 2002, Fitzgibbons 2009, Fizan 2010, Christensen 2010

Target population

A preventive therapy for all preterm infants at risk of NEC

Current clinical NEC progression



Target label population

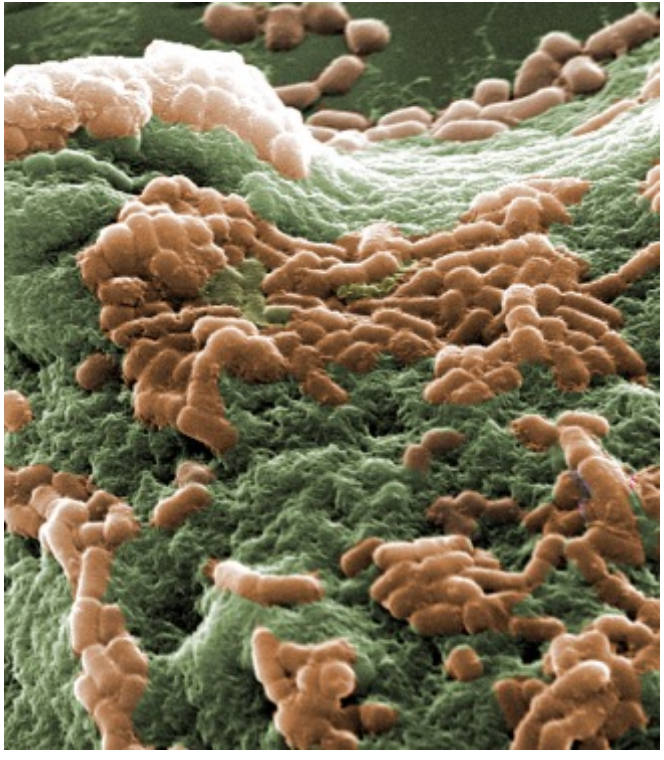
Based on the expected IBP-9414 drug label, the targeted annual label population is:

- **US:** 56,000 premature infants (≤1500 gram)
- **EU5:** 108,000 premature infants (≤ 34 weeks)

Approximately 162,000 premature infants at risk of NEC are born each year in US and EU5

Lactobacillus reuteri

Active substance of IBP-9414



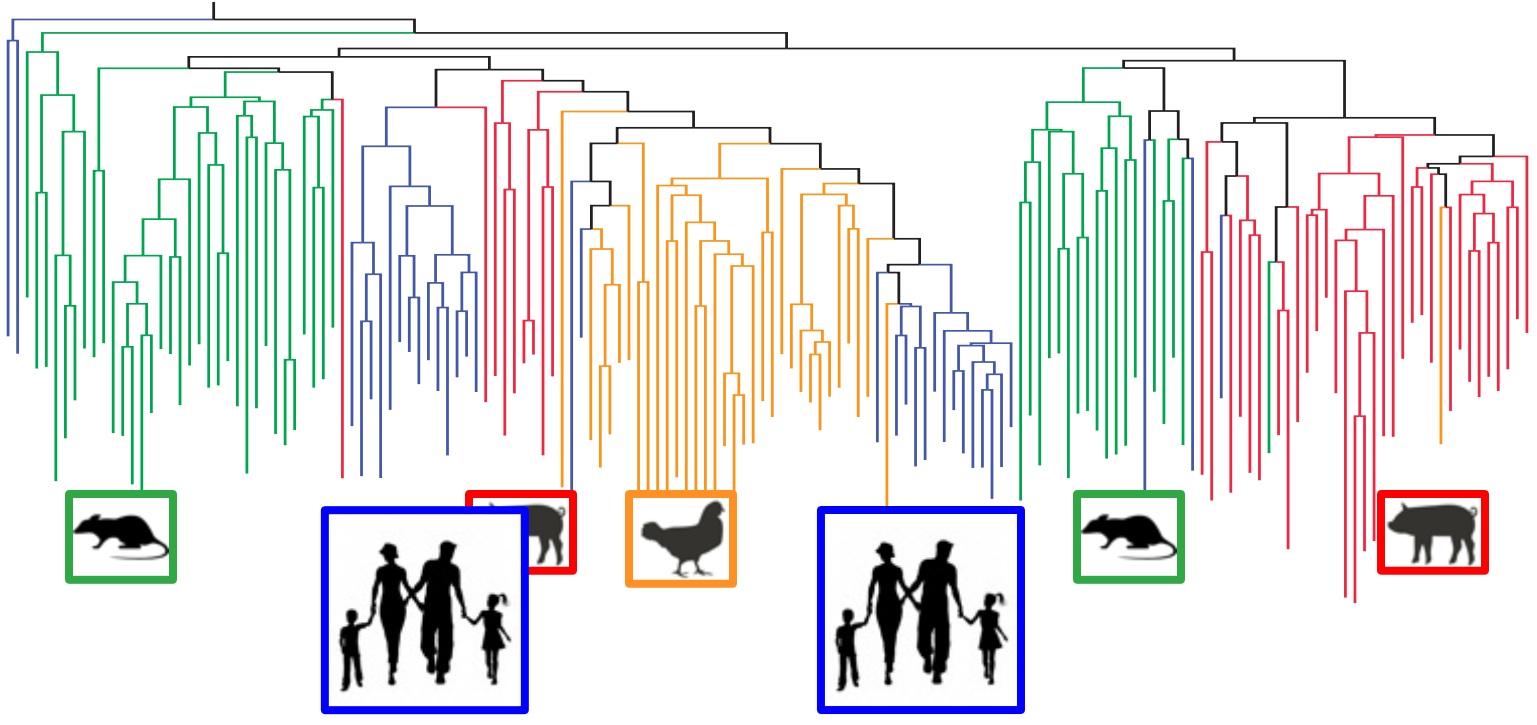
Lactobacillus reuteri (orange) adhering to intestinal mucus

Lactobacillus reuteri present on women's breasts

Picture with the permission Versalovic

Evolutionary adaptation of *L. reuteri* to the human gut

Genetic relatedness of global *L. reuteri* genomes



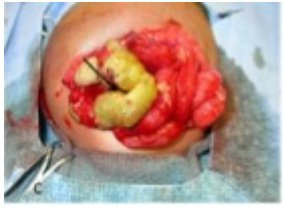
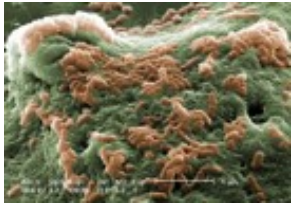
L. reuteri shares a long evolutionary history in the human gut and in human breast milk

L. reuteri is a true human gut symbiont with mutual benefit to both human host and bacterium

Source Oh 2010, Walter 2011

L. reuteri an ideal candidate for NEC

L. reuteri has strain-specific attributes which affect the NEC pathogenesis

Major processes involved in NEC	*L. reuteri* strain-specific benefits
	
Dysbiosis	Anti-pathogen effects
Impaired gut motility	Improvement of gut motility
Unregulated Inflammation	Anti-inflammatory effects

Source Neu and Walker 2011, *L. reuteri* picture with the permission Versalovic

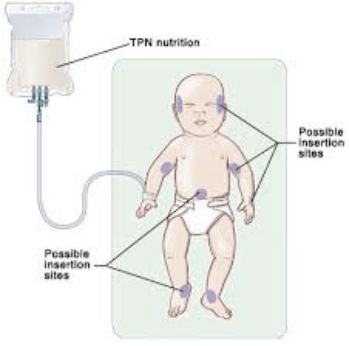
Clear efficacy signal from *L. reuteri*

All studies show clinically significant reduction of NEC

Study	Number of patients	Reduction in NEC incidence
Rojas et al. (2012)	▪ 750 patients	▪ 40% in the total study population ▪ 37% in infants ≤1,500g
Oncel et al. (2014)	▪ 400 patients	▪ 20% in the total study population ▪ 38% in infants ≤1,000g
Hunter et al. (2012) & Dimaguila et al. (2013)	▪ 354 patients	▪ 89% in the total study population
Sanchez Alvarado (2017)	▪ 225 patients	▪ 64% in infants ≤1,500g
Rolnitsky et al. (2018)	▪ 937 patients	▪ 49% in the total study population ▪ 52% in infants ≤1,500g ▪ 55% in infants ≤1,000g
Jerkovic Raguz et al. (2016)	▪ 100 patients	▪ 50% in the total study population
Shadkam et al. (2015)	▪ 60 patients	▪ 82% in the total study population
Hernandez-Enriquez et al. (2016)	▪ 44 patients	▪ 92% in the total study population

Potential benefit to all premature infants

Premature infants are extremely difficult to feed
Infants require intravenous fluids solution for brain and body
Intravenous nutrition is inadequate
IV nutrition (TPN) can also be toxic to the liver

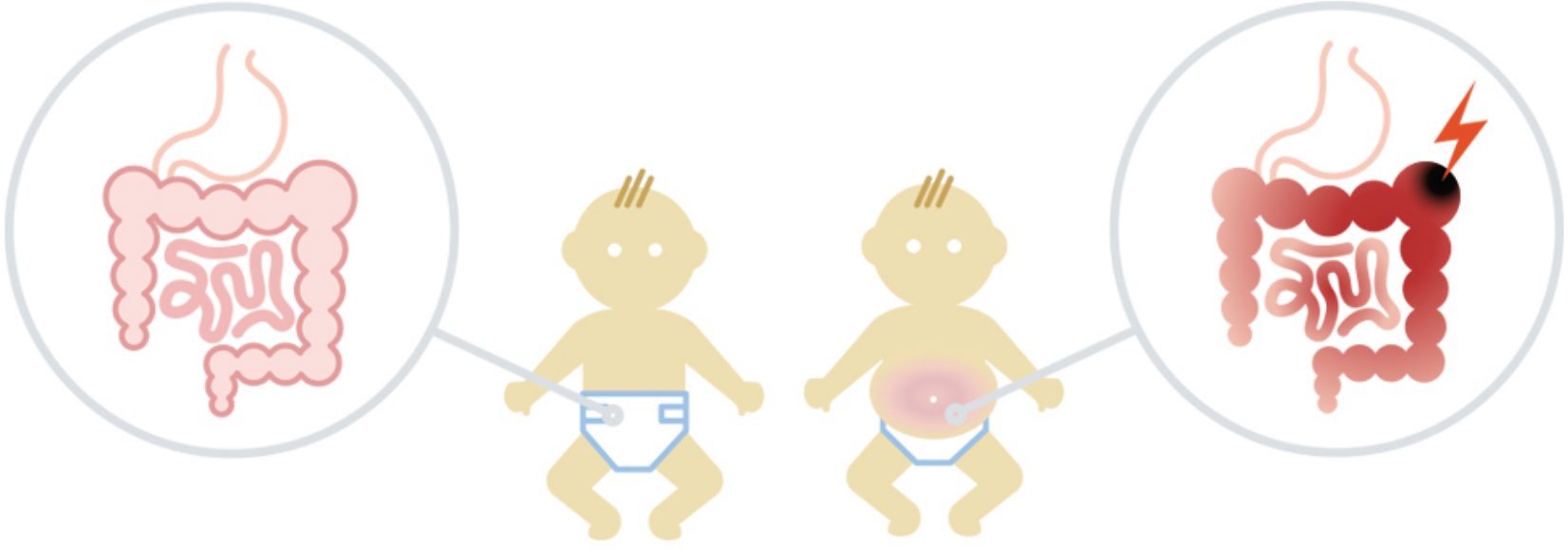


L. Reuteri demonstrates clear signal on improved feeding tolerance

Improved feeding tolerance in preterm infants

Study	Number of patients	Results
Rojas et al. (2012)	▪ 750 patients	▪ 34% reduction in episodes of feeding intolerance with interruption of feeding (p=0.08)
Oncel, et al. (2014)	▪ 400 patients	▪ 29% reduction in episodes of feeding intolerance with interruption of feeding (p=0.015) ▪ 10% reduction in time to full enteral feeding (p=0.006)
Oncel et al. (2015)	▪ 300 patients	▪ 36% reduction in episodes of feeding intolerance with interruption of feeding (p=0.004)
Rolnitsky et al. (2018)	▪ 937 patients	▪ 52% reduction in episodes of feeding intolerance with interruption of feeding (p<0.01)

Economic burden of NEC



Major surgery required in 20-40% of NEC cases at cost of 300 kUSD or more

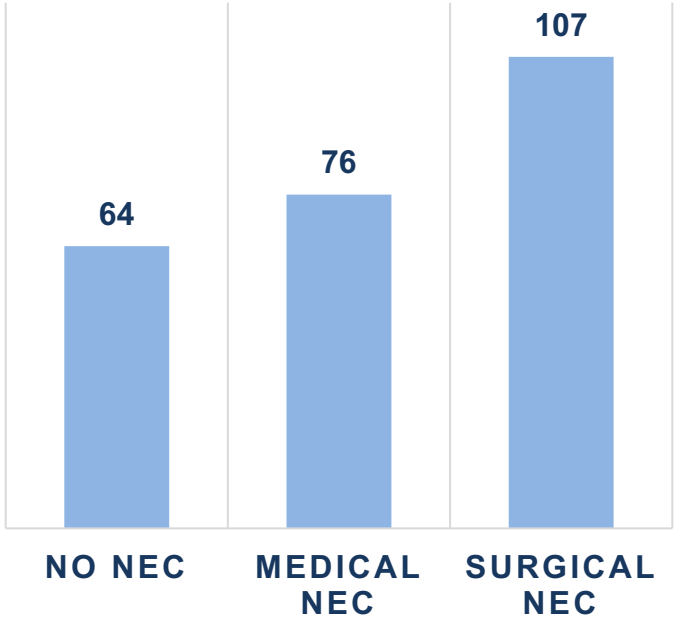
Survivors have long-term consequences: short-bowel syndrome, abnormal growth, cognitive, visual and hearing impairments

The economic cost of NEC is estimated to be USD 5 Billion for hospitalization in the US*

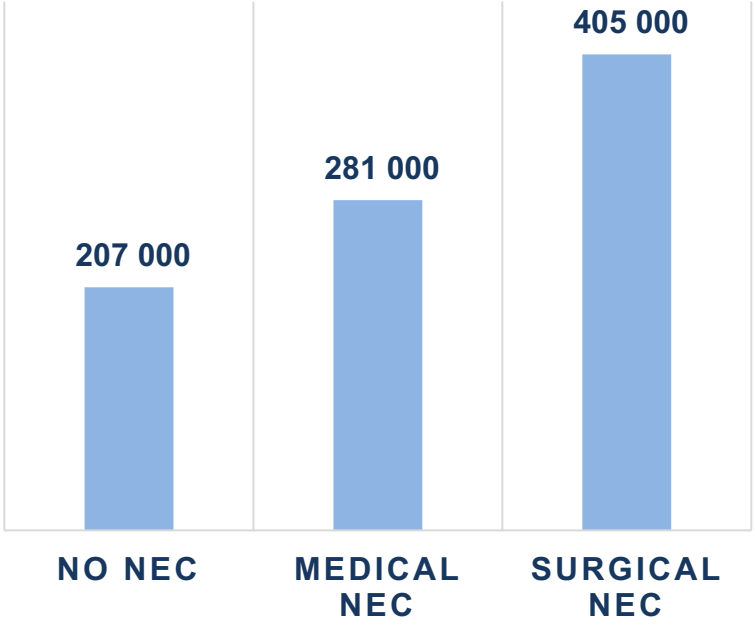
* Sheila M. Gephart et al, 2012

Economic burden of NEC

Prolonged days of hospital stay*

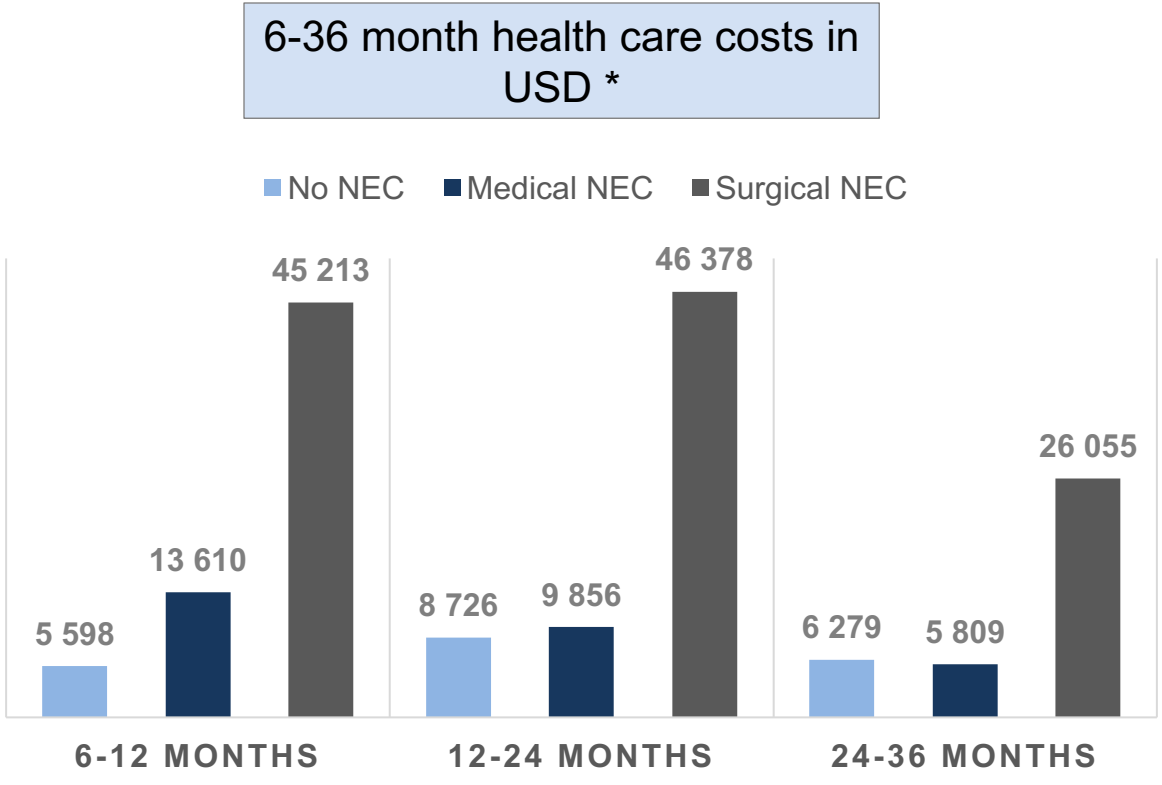


Initial hospitalization costs in USD*



*Ganapathy et al, 2011; For infants ≤ 28 weeks of gestational age

Extended economic burden of NEC



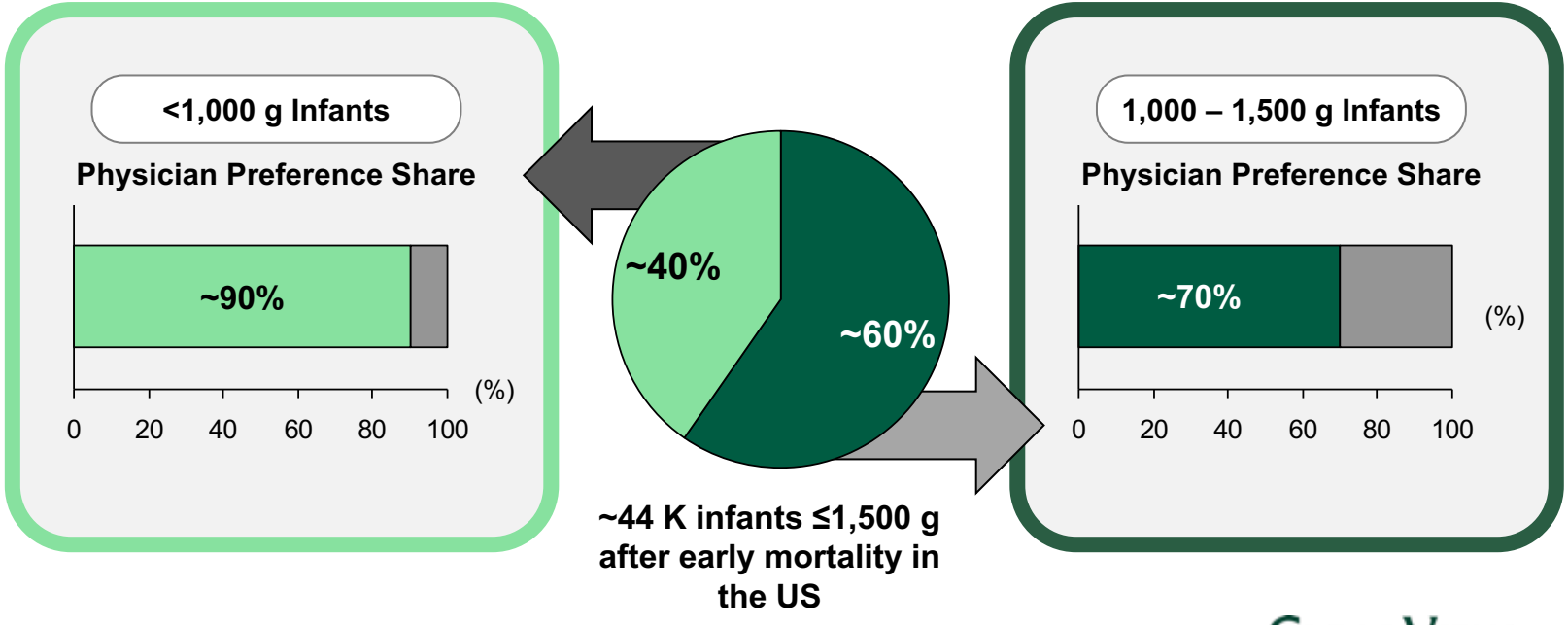
And long term costs associated with sequelae such as

impaired growth, short bowel syndrome, poor long-term neurodevelopment

* Ganapathy et al, 2013

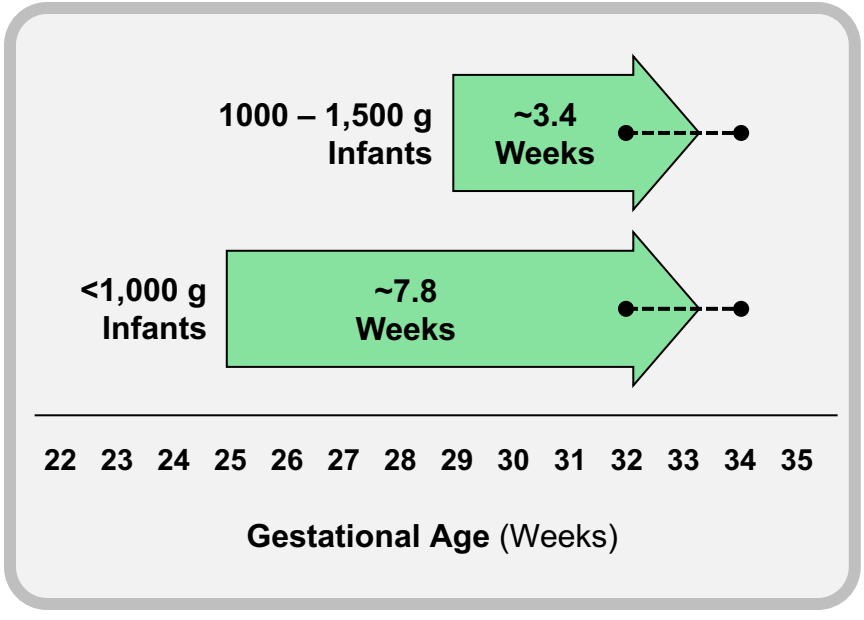
Neonatologists show high willingness to prescribe IBP-9414

Clearview US market research indicates an overall 78% physician preference share reflecting a high unmet medical need



ClearView Healthcare Partners

Treatment up to 34 weeks



Physicians expected to halt IBP-9414 treatment once infants had reached 32 to 34 weeks postmenstrual age

ClearView Healthcare Partners

Expected Formulary Inclusion by Institution Type

In the United States, high adoption in hospitals is anticipated in institutions which have the biggest share of premature infants

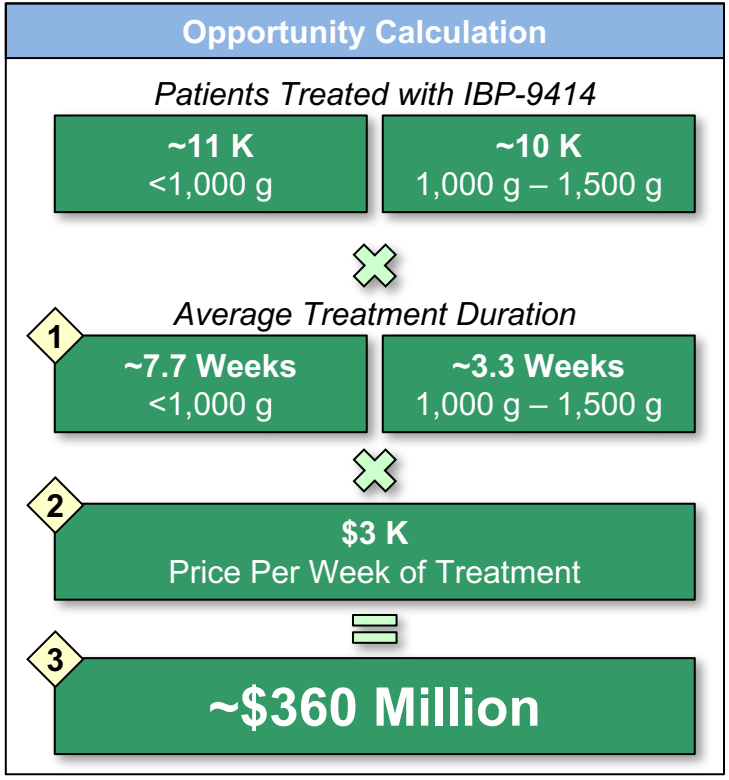
Institution Type	Major Medical Centers	Medium Hospitals	Small Community Hospitals
Share of Premature Infants	~60%	~30%	~10%
Estimated Formulary Adoption	~85%	~60%	~0%
Overall Formulary Inclusion	Approximately 70% of addressable patients are anticipated to receive care at an institution that includes IBP-9414 on formulary		

ClearView Healthcare Partners

Commercial Opportunity

Assuming a price of $3 K per week of treatment, IBP-9414 is expected to achieve sales of ~$360 M

IBP-9414 Commercial Opportunity



Key Considerations

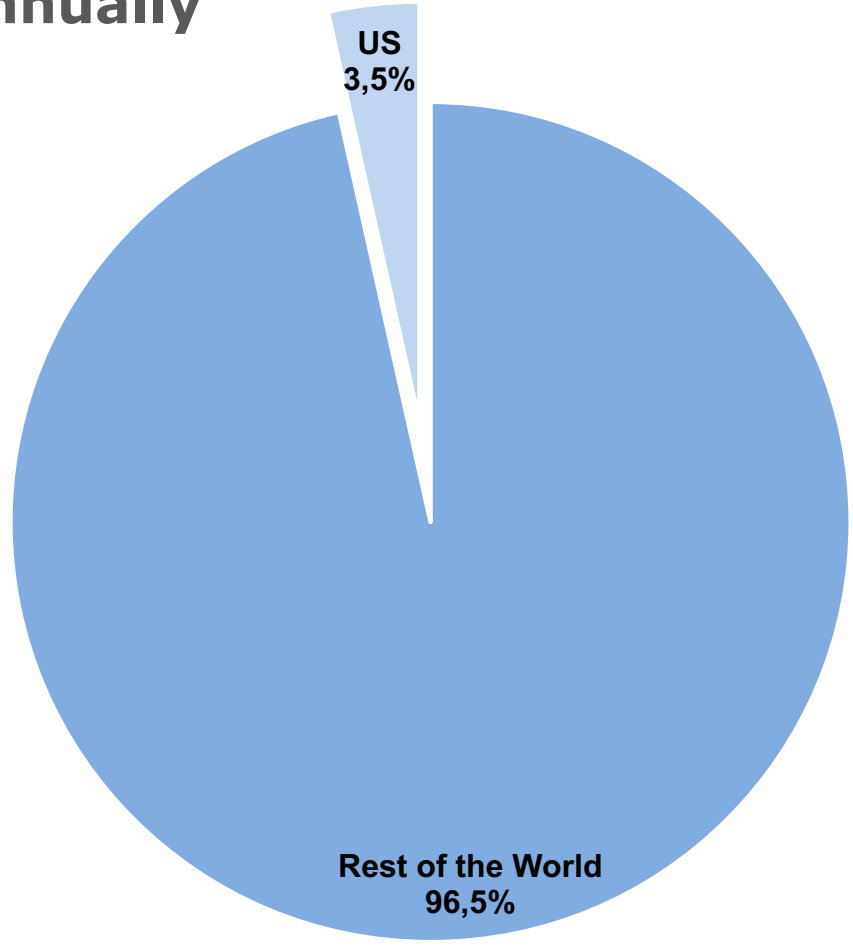
1. **Average treatment durations of ~7.7 and ~3.3 weeks are expected, based on physician preference and protocol restrictions**
   - Distribution of infants weighing ≤1,500 g and surviving greater than six days from birth by gestational age was used to calculate average durations
2. **Both $3 K per week and $2 K per week price points were tested to understand impact on formulary inclusion and potential protocol restrictions**
   - Given the two price points, P&T members did not expect the lesser price to promote significantly decreased restrictions
3. **Sales are estimated to be ~$360 million assuming a $3 K per week price point**
   - IBP-9414 will likely achieve rapid uptake given the product's value proposition

ClearView Healthcare Partners

Global preterm births

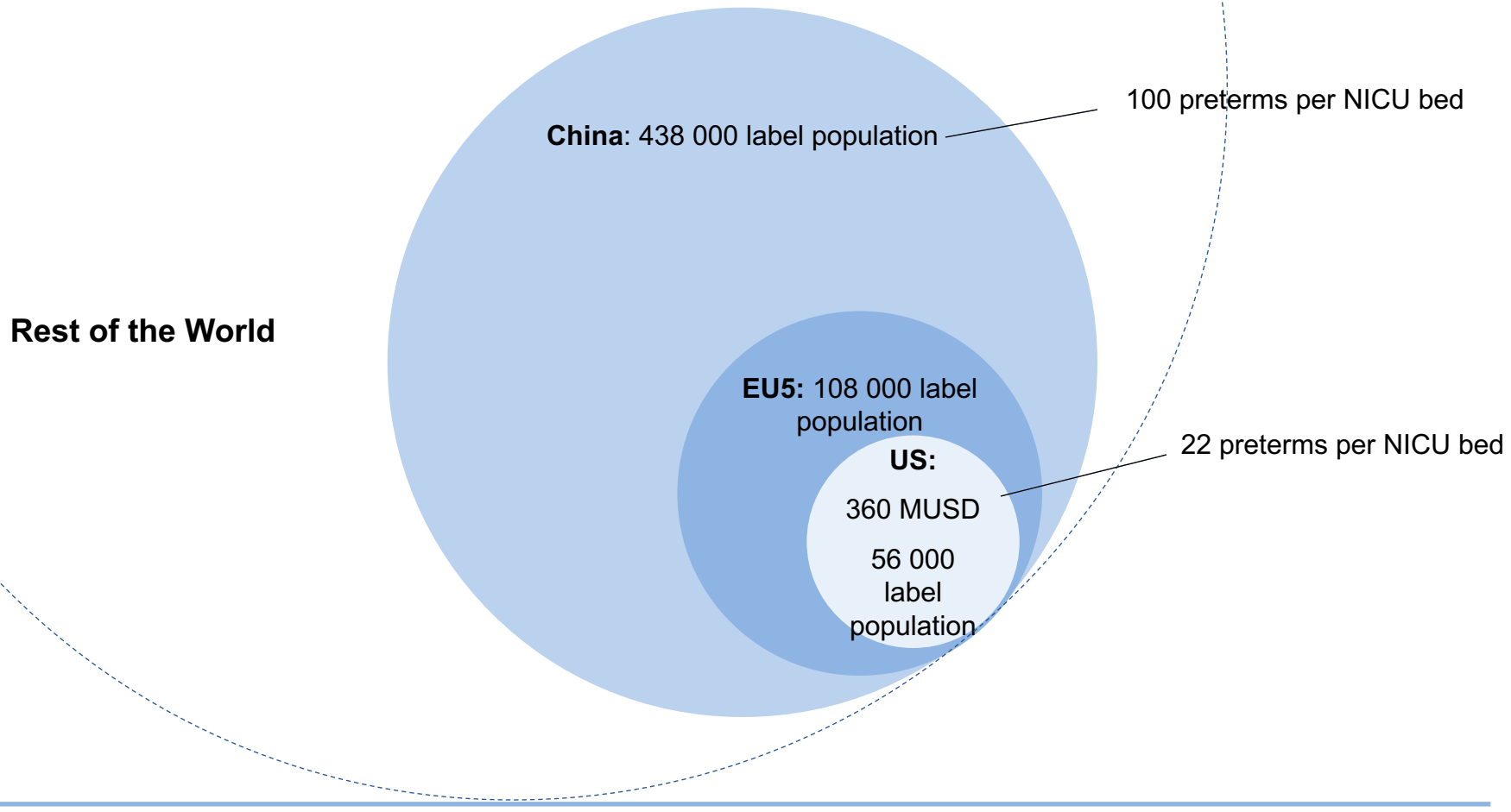
15 Million preterm births annually

Preterm birth rates are increasing in almost all countries with reliable data



Source H. Blencowe et al. 2012

A globally valuable pharmaceutical



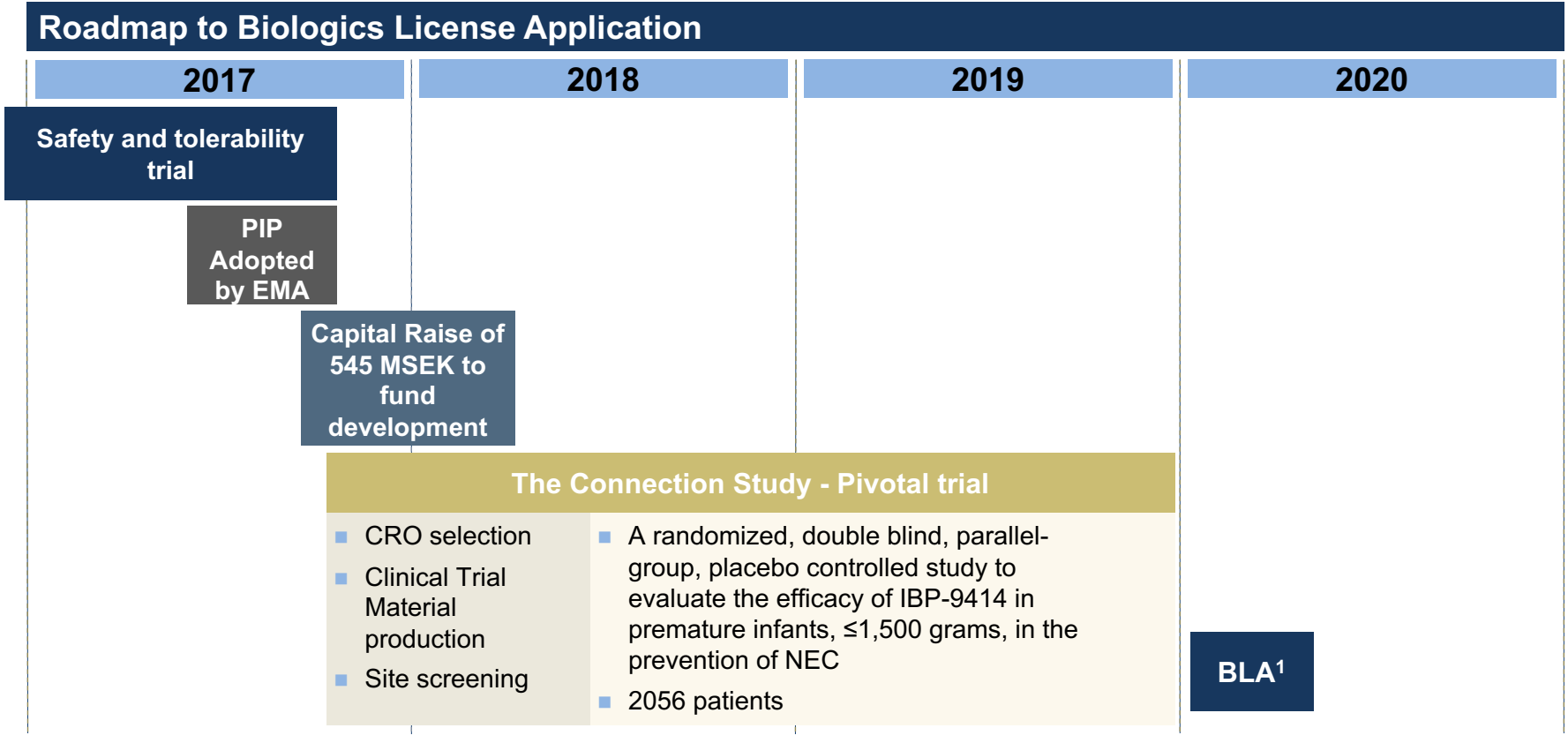
IBP-9414's eligibility for a Priority Review Voucher

- FDA granted Rare Pediatric Disease product status to IBT for IBP-9414, this means that IBT should be awarded a priority review voucher at the time of approval
- This voucher is transferrable and cannot expire. 18 vouchers were awarded by year end 2017
- Previous transactions:

2017	ultragenyx pharmaceutical	sold for $130M to	NOVARTIS
2017	BIOMARIN	sold for $125M to *not disclosed yet*	
2017	SAREPTA THERAPEUTICS	sold for $125M to	GILEAD *used*
2016	Knight	sold for $125M to	GILEAD *used*
2016	PaxVax	sold for $200M to	GILEAD
2015	United Therapeutics	sold for $350M to	abbvie
2015	Asklepion	sold for $245M to	SANOFI *used*
2014	BIOMARIN	sold for $67.5M to	REGENERON SANOFI *used*

IBP-9414 – Roadmap

Development program in accordance with advice from regulators and KOLs



Notes

1 Biologics License Application

IBP-9414 Safety and Tolerability study

Conclusions

- Recruitment rate was higher than estimated without a difference between big and small babies
- Demographics of the study was representative of the target population
- Similar Adverse Event and Serious Adverse Event profile between active and placebo groups
- No SAE related to study drug

IBP-9414 Safety and Tolerability study

Conclusions cont.

- No evidence of cross-contamination with IBP-9414 in placebo treated infants
- Treatment with IBP-9414 leads to presence of bacterium in the feces on day of last dose
- Smaller infants needed the higher dose to display IBP-9414 in the feces
- 30 days after last dose, the bacteria have been washed out

The study shows that IBP-9414 is safe and tolerable

Manufacturing Process of IBP-9414

Stringent control of manufacturing environment

Cell Bank

Pre-culture

Fermentation

Filtration

Mixing

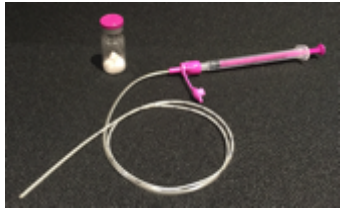
Formulated Cell Suspension

Filling

Freeze-drying

Packaging & Labelling

IBP-9414
powder for oral suspension



IBP-9414 for the prevention of necrotizing enterocolitis

IBP-9414 is based on all relevant pillars for the development of a successful drug

- Medical need ✓
- Mechanism of action ✓
- Clinical data ✓
- Safe ✓
- Aligned regulatory agencies ✓
- GMP manufacture ✓
- Market exclusivity ✓
- Aligned payers ✓
- Priority review voucher eligibility ✓

Thank you!

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