Infant Bacterial Therapeutics

September 5, 2019

Staffan Strömberg, CEO

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First distribution deal for IBP-9414 in place

Agreement with Megapharm for IBP-9414 for the Israeli market and the Palestinian Authority's territories.

- Collaborate to include Israeli medical centers in Phase III trial
- Megapharm responsible for local registration, price negotiation and marketing
- IBT will receive 70% of revenue after an initial period

Infant Bacterial Therapeutics AB

Founded in 2013 in Stockholm, Sweden

IPO in 2016, currently listed on Nasdaq Stockholm

- Market cap SEK 2 500 M ($258 M)
- Cash position as of June 30, 2019 SEK 540 M ($55 M) sufficient to fund IBP-9414 to market

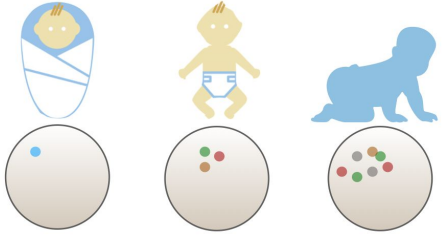
Pivotal Phase III Trial for our lead development program IBP-9414

- Patients recruited in EU and US
- Orphan Drug Designation in EU and US
- Rare Pediatric Disease Designation

The IBT concept

- Altering the human microbiome to treat diseases related to poor gut function

- Newborn infant microbiome is dynamic



- Human bacterial strains derived from human breast milk

- Published clinical proof-of-concept signal

PEDIATRICS
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

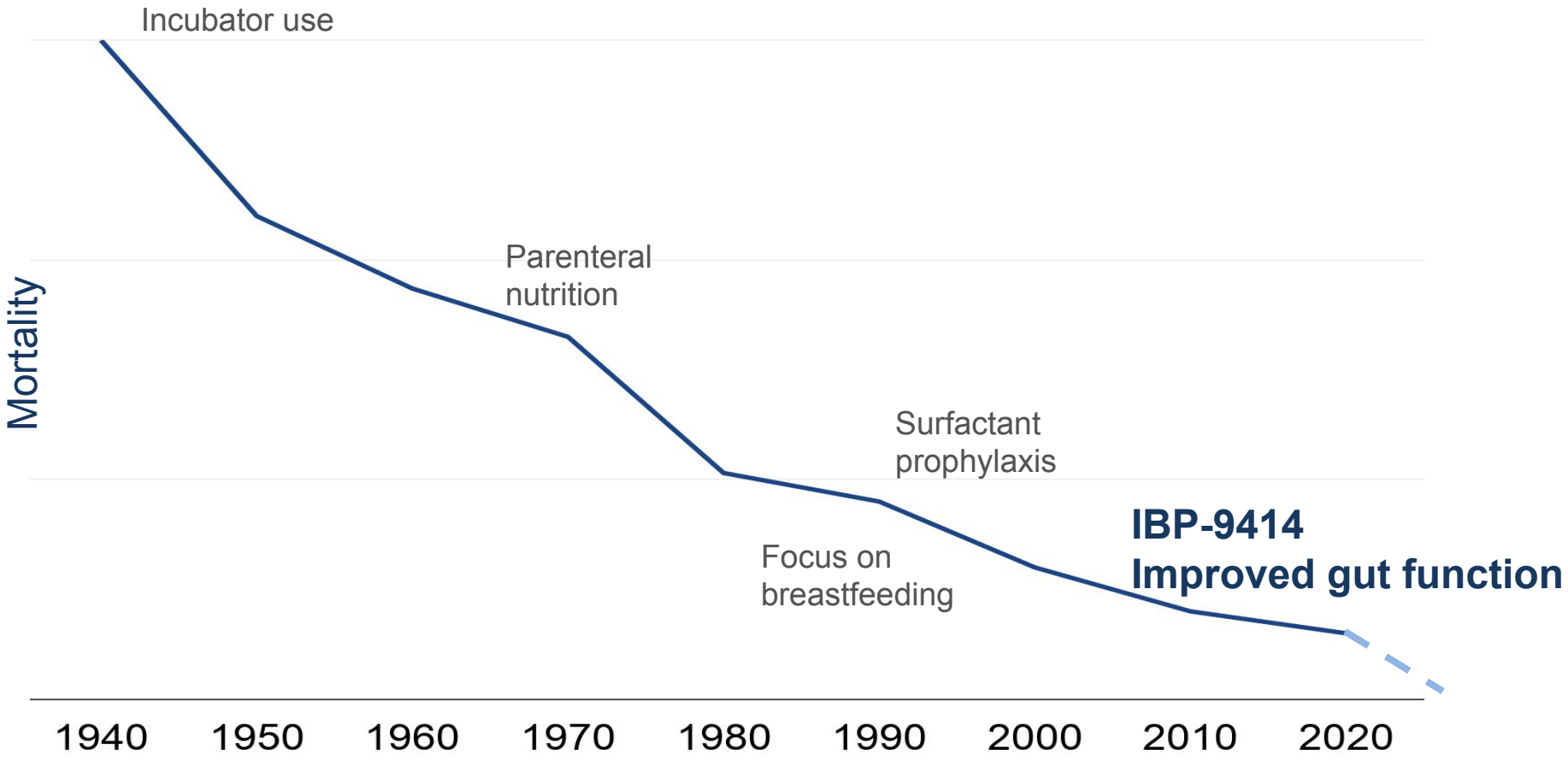
Prophylactic Probiotics to Prevent Death and Nosocomial Infection in Preterm Infants

Mario A. Rojas, Juan M. Lozano, Maria X. Rojas, Viviana A. Rodriguez, Martin A. Rondon, Jaime A. Bastidas, Luis A. Perez, Catherine Rojas, Oscar Ovalle, Jorge E. Garcia-Harker, Maria E. Tamayo, Gloria C. Ruiz, Adriana Ballesteros, Maria M. Archila and Mauricio Arevalo

Pediatrics 2012;130;e1113; originally published online October 15, 2012; DOI: 10.1542/peds.2011-3584

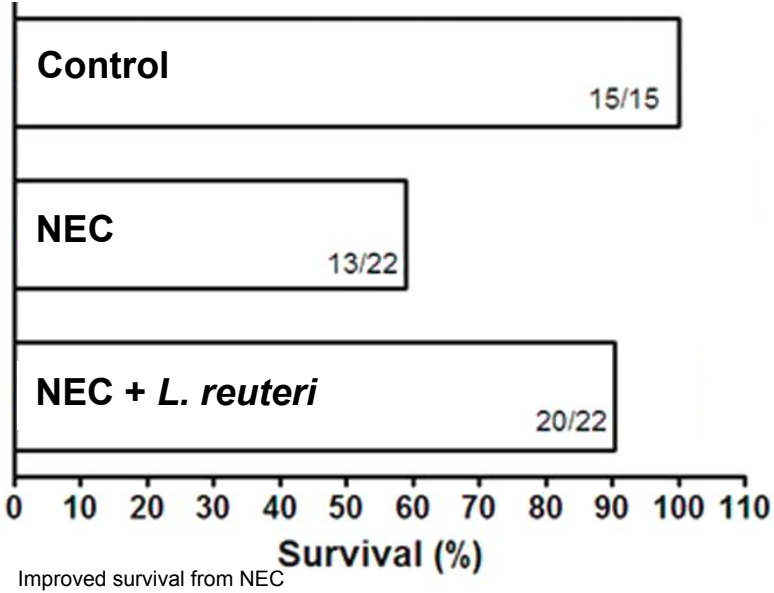
IBP-9414 in Phase III
High unmet medical need

Breakthroughs in preterm infant care

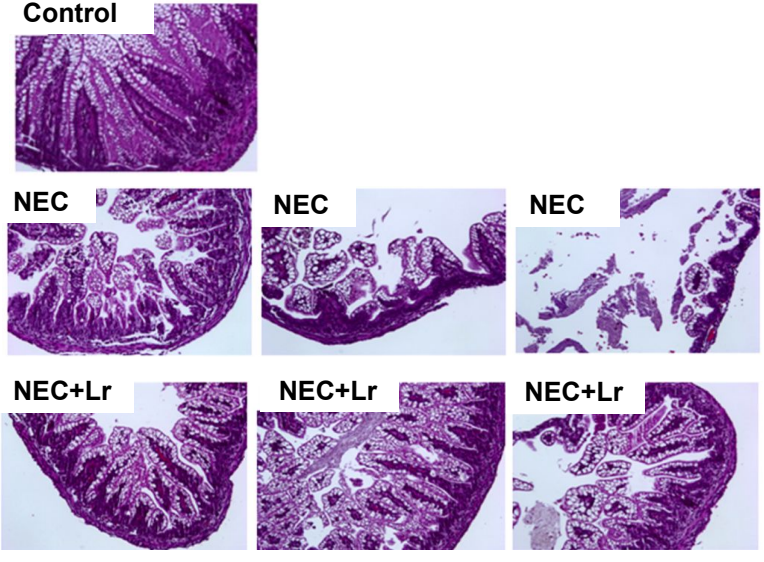


CDC/NCHS, National Vital Statistics System

L. reuteri protects from NEC in animal models



Improved survival from NEC



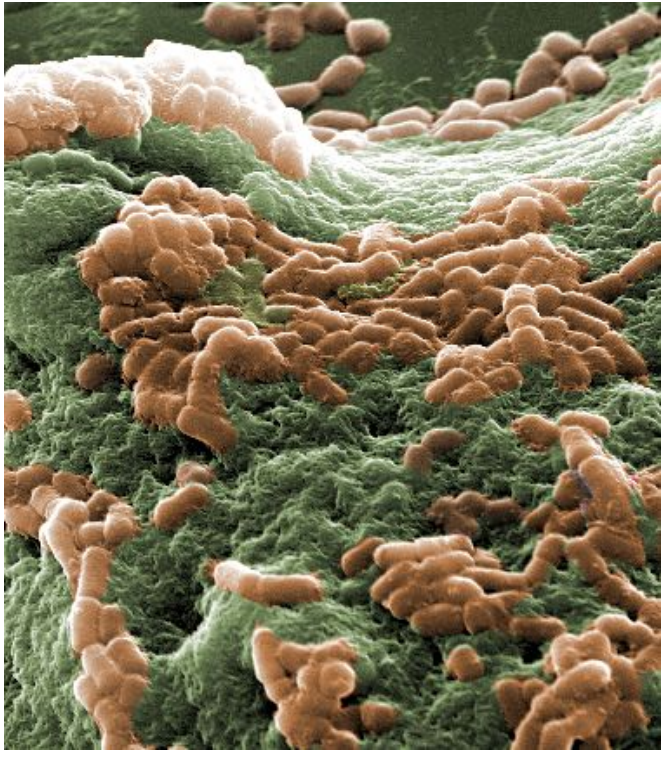
Reduced intestinal damage

Liu, 2012, 2013, 2014

Lactobacillus reuteri

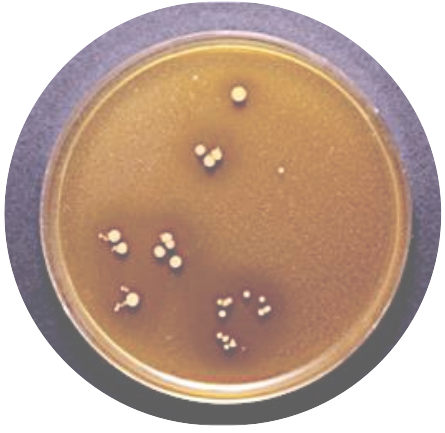
Active substance of IBP-9414

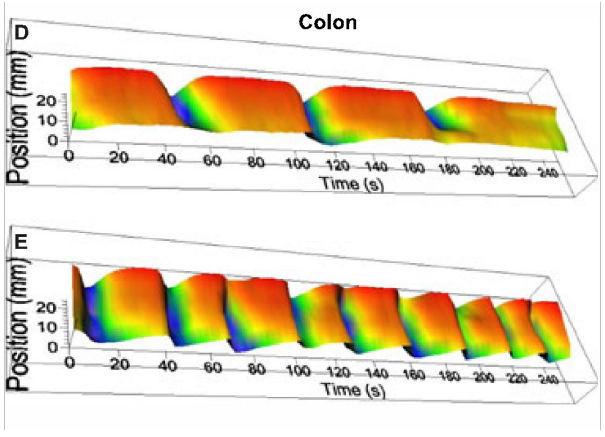
Lactobacillus reuteri present on women's breasts



Lactobacillus reuteri (orange) adhering to intestinal mucus

L. reuteri - mechanisms of action in the GI tract





Combats dysbiosis

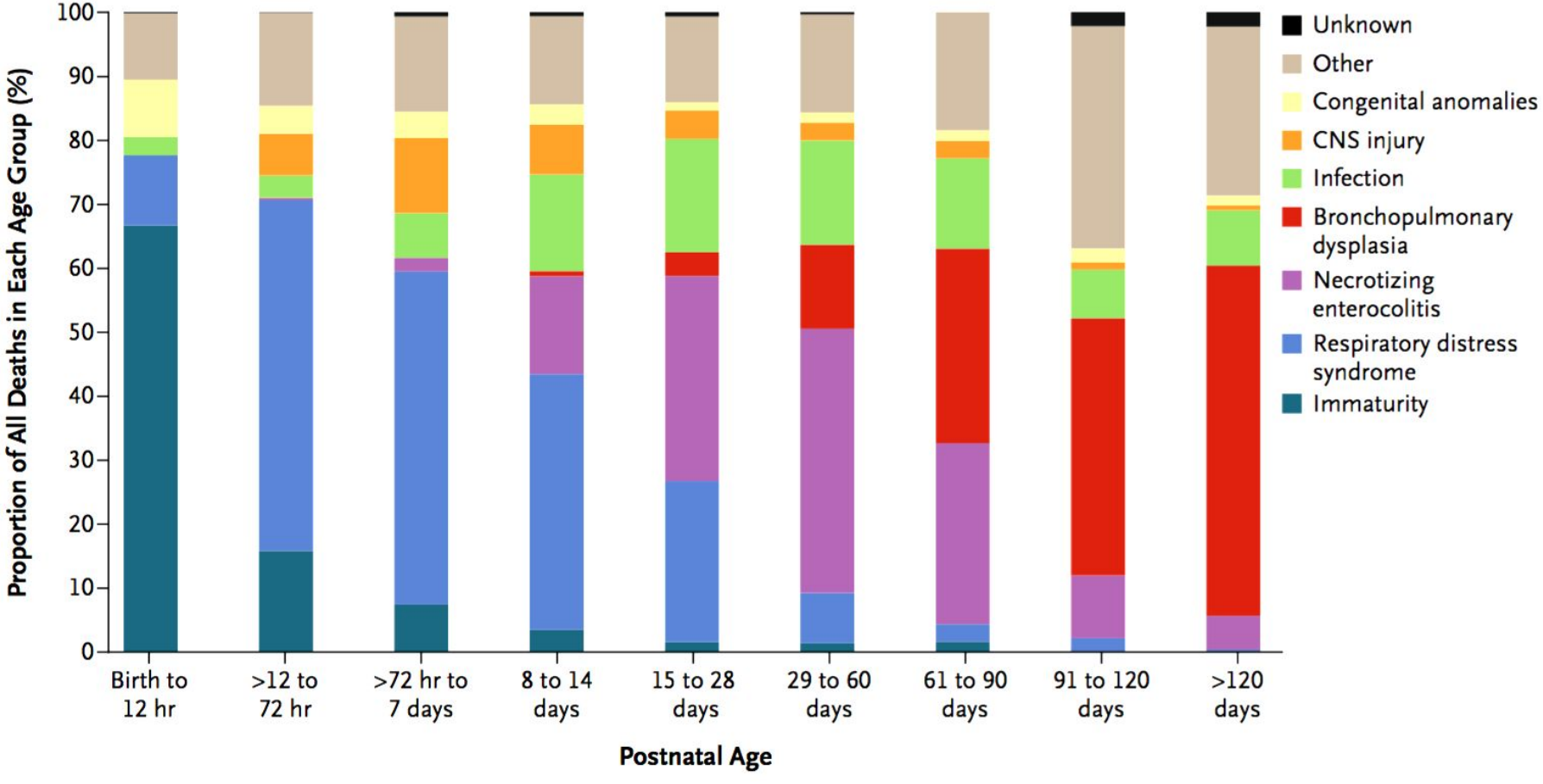
Reduces inflammation

Improves gut motility

Improved gut function including prevention of NEC

Schaefer 2010, Walter 2011, Wu 2013

Causes of death



Patel 2015

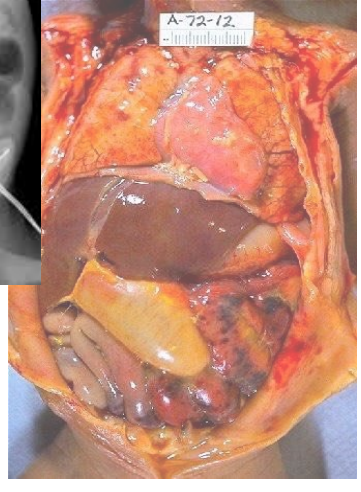
Necrotizing enterocolitis (NEC)

- NEC is severe inflammation of the bowel in preterm infant where 20-40% need complicated and costly surgery

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

- There is no therapy available today

NEC is one of the leading causes of death in the Neonatal intensive care unit (NICU) with up to 40% mortality rate killing 1500 US and 3700 EU infants each year

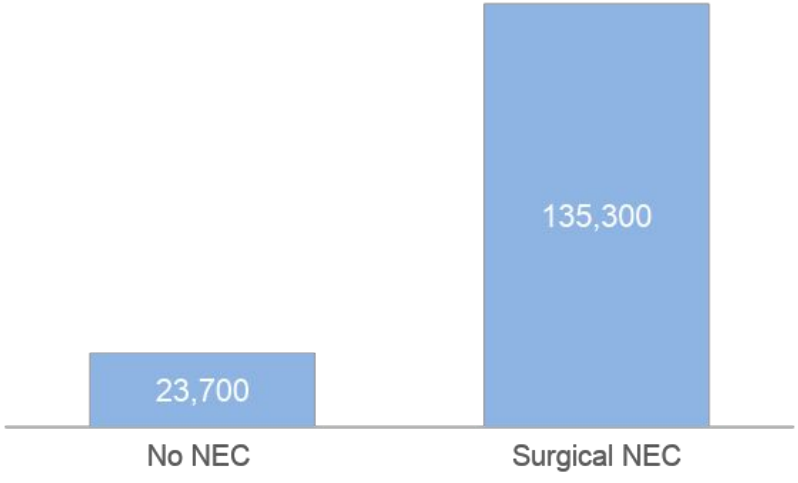


Simpson 2010, Clark 2012

Economic burden of NEC

NEC Economic Burden is estimated to be 20% of the total cost of initial care and USD 5 Billion spent annually on NEC in the US.

Costs continue after NICU discharge



Accumulated cost USD between 6-36 months

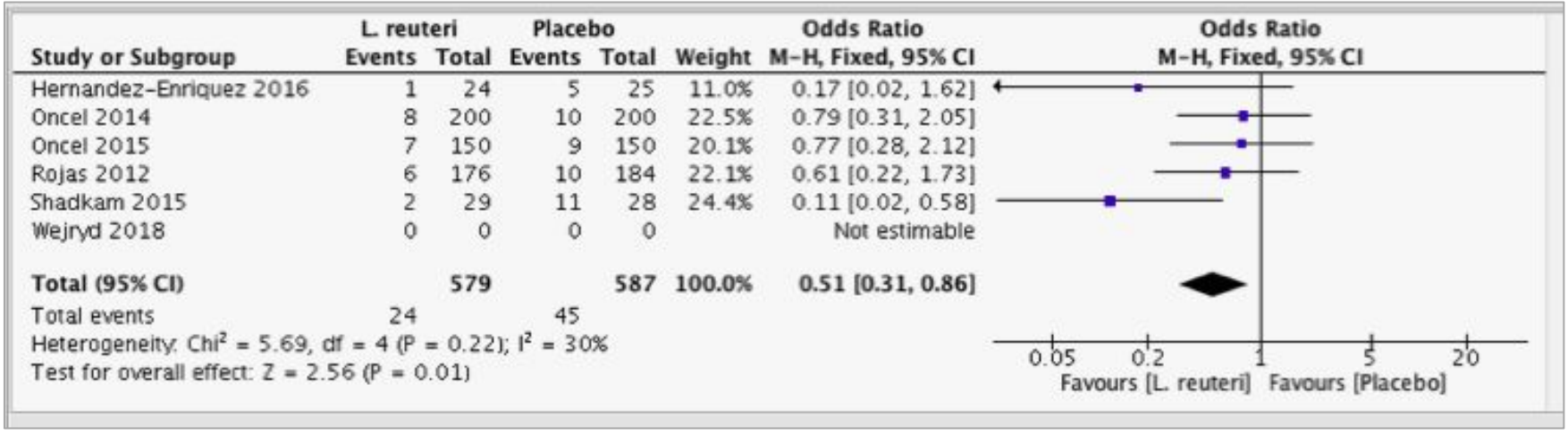
Long term costs associated with sequelae such as impaired growth, short bowel syndrome and poor neurodevelopment

Ganapathy 2011, 2013

Publications with clinical signal of NEC reduction

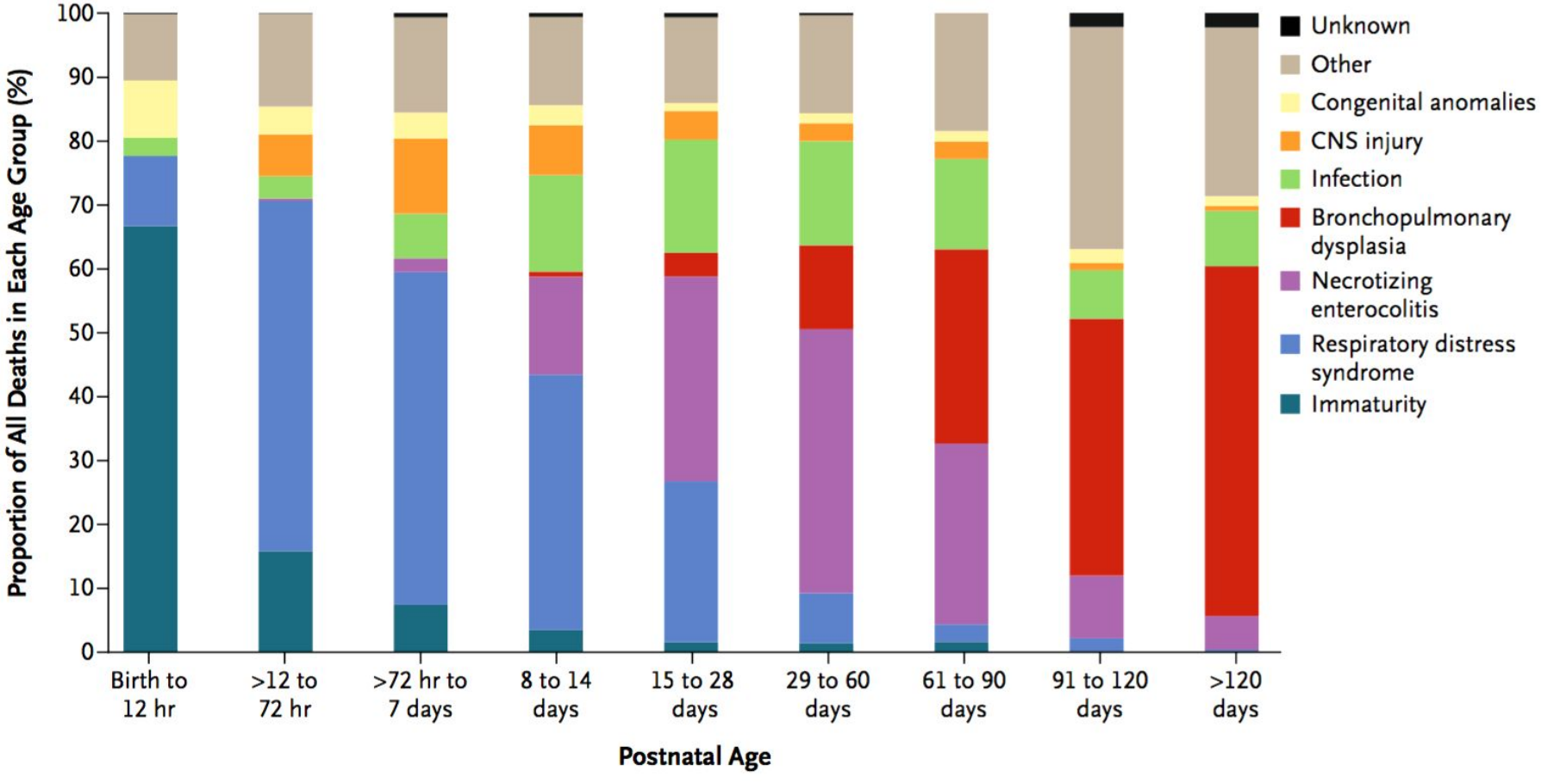
	Number of Infants	NEC incidence		
		Control		With L. reuteri
Rojas et al. 2012	750	5,4 %	↘	3,4 %
Oncel et al. 2014	400	5,0 %	↘	4,0 %
Oncel et al. 2015	300	6,0 %	↘	4,7 %
Shadkam et al. 2015	60	36,7 %	↘	6,7 %
Hernandez-Enriquez et al. 2016	44	25,0 %	↘	4,2 %
Spreckels et al. 2018	104	9,0 %	↘	4,0 %
Wejryd et al. 2019	134	12,0 %	↘	10,0 %
Hunter et al. 2012/Dimaguila et al. 2013	354	15,1 %	↘	1,6 %
Sanchez-Alvarado 2017	225	14,6 %	↘	5,3 %
Rolnitsky et al. 2017	937	6,0 %	↘	2,9 %
Jerkovic-Raguz et al. 2016	100	8,0 %	↘	4,0 %

NEC clinical signals



Meta-analysis: NEC <1500g all randomized controlled trials gives an Odds Ratio of 0.51

Causes of death



Patel 2015

Feeding the preterm infant

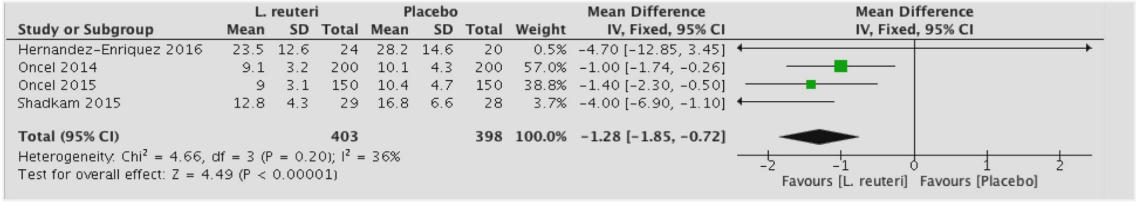
Establishing enteral (mouth) feeding in preterm infants is a primary clinical goal to **attain normal growth,** important for e.g. cognitive development.

Prolonged parenteral (needle feeding) nutrition increases cost and **causes complications** including: cholestasis, increased risk of **BPD**, pulmonary vascular resistance, **infections and sepsis**.

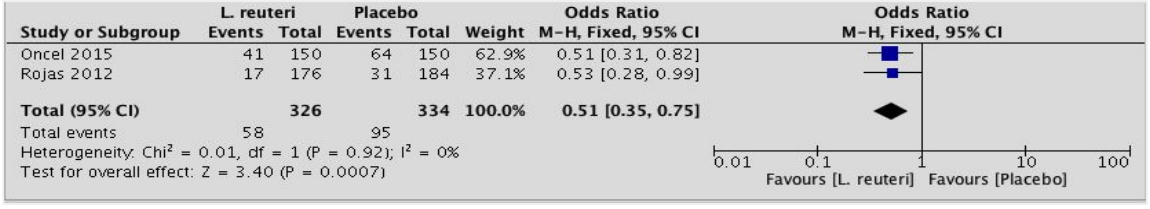
Murgas-Torrazza, 2013; Agostoni, 2010

Feeding Tolerance - clinical signals and consequences

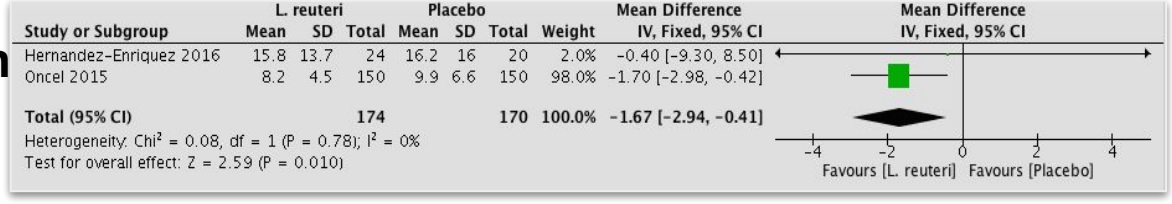
Time to full enteral feeding
-1.28 days [-1.85, -0.72]



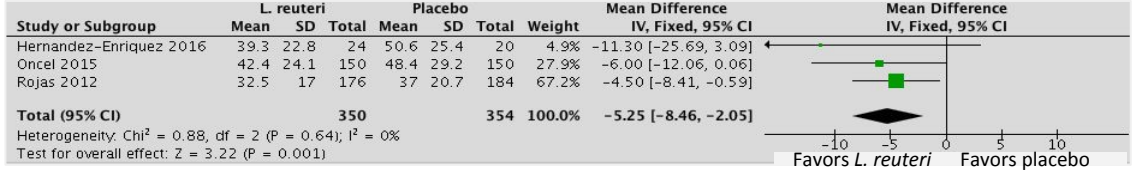
Feeding intolerance events
OR 0.51 [0.35, 0.75]



Days on Parenteral Nutrition
-1.67 days [-2.94, -0.41]



Days in hospital
-5.25 days [-8.46, -2.05]




Regulatory agencies and KOLs

Endorsed Phase III Pivotal Trial

- IBT has developed the IBP-9414 program in cooperation with the regulators and with considerations of KOLs experience and clinical practice

- CTX/IND approval received in UK, Spain, Hungary, France and USA, application filed in Israel

FDA U.S. FOOD & DRUG ADMINISTRATION

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Phase III: The Connection Study design

Multiple primary endpoint study

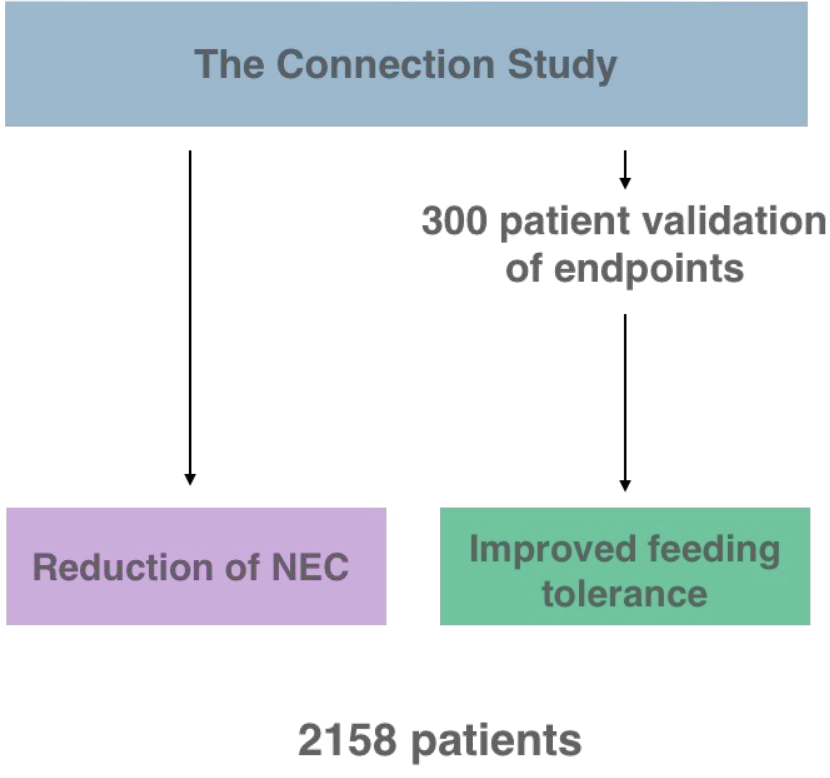
Primary objective: Evaluate the efficacy of IBP-9414 vs. Placebo on the prevention of NEC and on sustained feeding tolerance

Inclusion: Birth 23 - 32 weeks gestation, 500g -1500 g birth weight

First dose: Within 48 hours of birth

Treatment period: up to 12 weeks

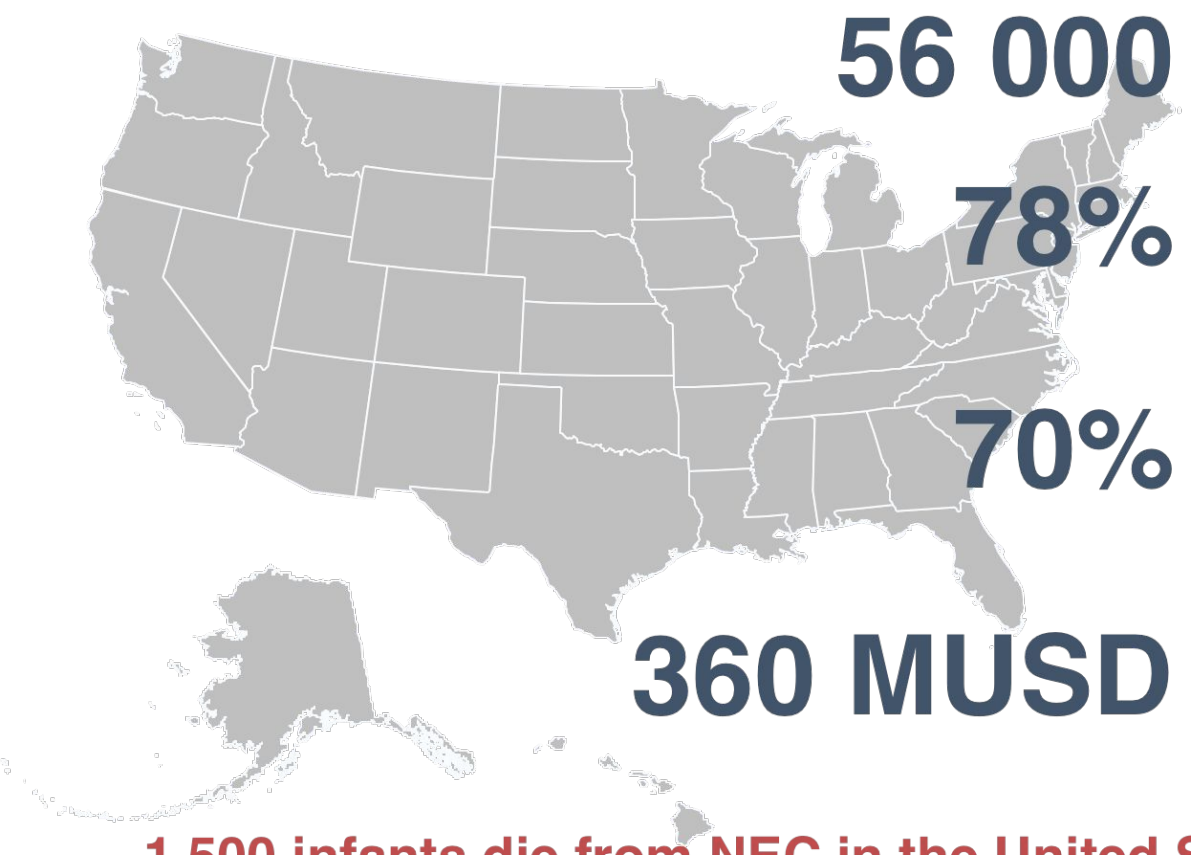
Follow-up: 5 weeks




STRONG INTEREST FROM THE MARKET

A valuable pharmaceutical

Results of market analysis by ClearView Healthcare Partners



56 000

Number of infants born under 1,500 grams in the United States annually

78%

Physician preference share demonstrates neonatologists show high willingness to prescribe IBP-9414

70%

Of addressable patients are anticipated to receive care at an institution that includes IBP-9414 on formulary

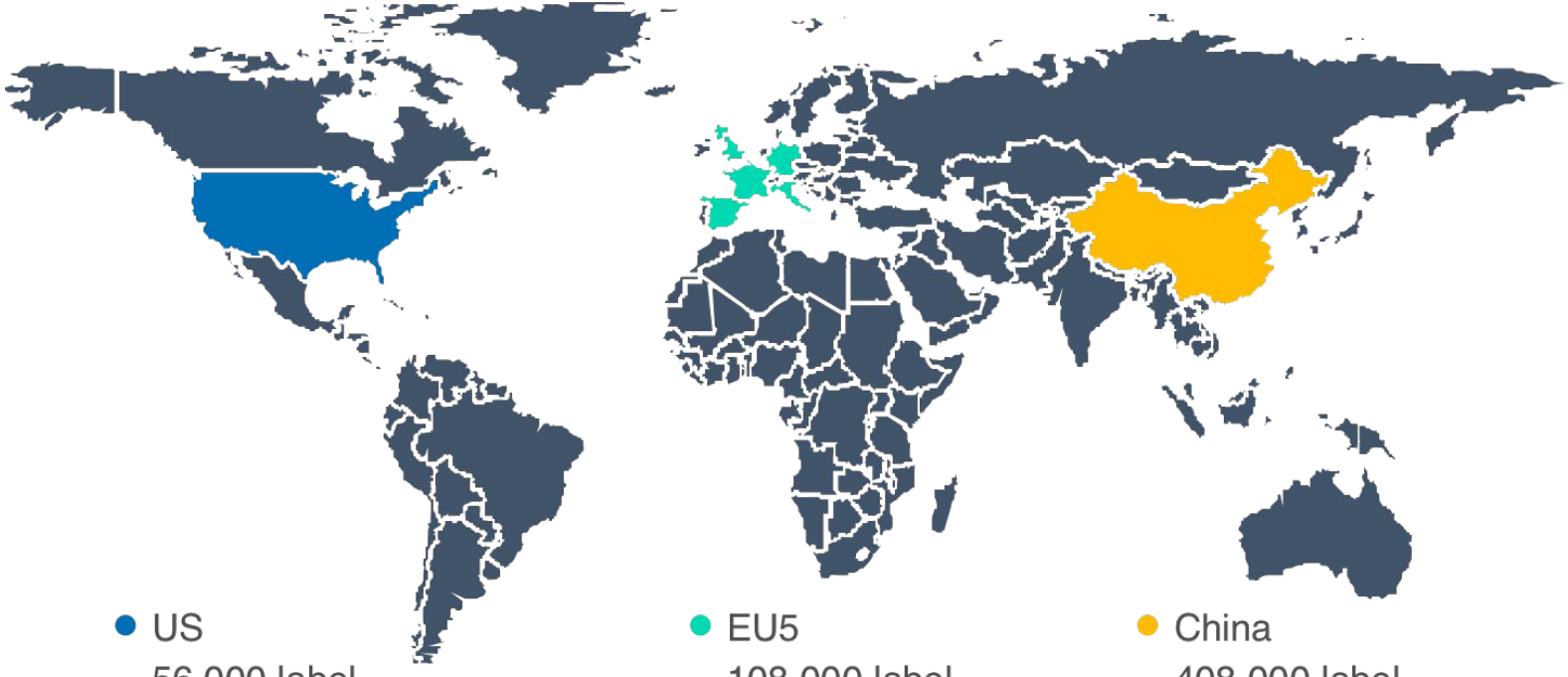
360 MUSD

Estimated annual revenue potential in US based on ClearView market research

1 500 infants die from NEC in the United States each year

A global need

15 Million Pre-term births annually



- US
  56 000 label population = 360 MUSD annual sales for NEC prevention
- EU5
  108 000 label population
- China
  408 000 label population

IBP-9414 our lead Phase III program

Ticks 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 ✓


Thank you
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