INFANT BACTERIAL THERAPEUTICS

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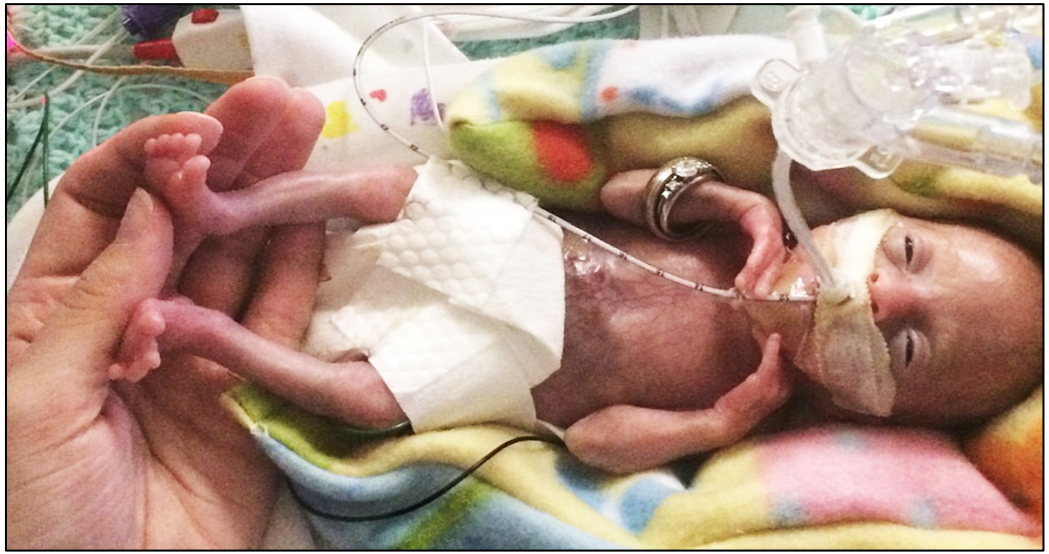
IBT in Short

- **Founded in in Sweden in 2013. IPO in 2016 at NASDAQ main market in Stockholm.**
- **IBT is currently developing the drug candidate IBP-9414, in clinical Phase III**
- **We are today the only company dosing bacteria to preterm infants under US IND**
- **The vision for IBP-9414 is to become the world's first approved pharmaceutical grade probiotic with the goal to prevent life threatening diseases in premature infants**

* Necrotizing enterocolitis

Major Unresolved Medical Needs in Preterm Babies



Preventive treatments are needed

There are no more vulnerable patients

The Connection Trial - first ever probiotic phase 3 study under US IND.

The Connection Trial

- Double blind, placebo-controlled, parallel group, multicenter phase 3 study.
- Preterm infants of BW 500-1500g and cGA 23-32w.
- Endpoints: Primary- Incidence of NEC and time to Sustained Feeding Tolerance (SFT).
- Secondary- Medical NEC, Surgical/autopsy NEC, mortality, weight gain, duration of hospitalization, feeding intolerance.
- IBP-9414 containing pharmaceutical grade *L. Reuteri* given enterally at a single daily dose of 10^9 CFU or sterile water placebo.
- Contributing centers in Bulgaria, France, Hungary, Israel, Poland, Romania, Serbia, Spain, UK, and US.

Pharmaceutical grade requires rigorous control

- Full pharmaceutical GMP (21 CFR Part 210/211) from cell banking to final product including raw materials, ingredients and excipients
- ICH stability and shelf-life determination
- Validated procedures for correct dosing

‘Connection Trial’- interim data on 708 ELBW infants

The present infant material

1. 708 infants included in a per-protocol defined safety analysis.
   a. 116 infants in 500-749g (mean 648g).
   b. 592 infants in the 750-1000g (mean 884g).
2. All data blinded to treatment- group allocation.
3. Clinical events collected from Investigator reports on adverse events.
4. Treatment period mean 52 days.

Dual analyses

1. Profile and frequency of serious adverse events (SAEs)
2. Event correlations to the time to SFT.

Profile and frequency of SAE* in infants of 500-749g and 750-1,000g

Outcomes

- **Infant mortality: 14 (12%) and 32 (5.4%)**
  - CoD dominated by cardiopulmonary SAEs (31%), sepsis (24%), NEC and IVH.
- **At least one SAE: 44 (38%) and 142 (24%)**
  - mean 0.57 SAEs per infant.
  - 50% SAEs occurred during first 2 weeks of life.
  - frequency inverse to BW and 3 times more common in the lower BW interval.
- **Infectious disorders (71 infants) most common SAE**
  - dominated by sepsis- septic shock (54 infants)
  - reported in 18.1% and 8.4%
- **Respiratory SAEs in 61 infants**
  - reported in 12.1 % and 7.9% and
  - included BPD in 5.2% vs 2.8%
- **Serious GI in 61 infants**
  - NEC in 7.8% and 3.7%
  - GI perforation in 4.3 and 2.4%
- **Serious IVH- intracranial hemorrhage in 6.9% and 3.6%**
- **PDA in 4.3% and 2.2%**
- **ROP in 3.4% vs 0.5%**

*deemed life-threatening or e.g., to prolong hospitalization by responsible Investigator

Profile and frequency of SAE in infants of 500-749g and 750-1,000g

Conclusion

- **Mortality lower than expected (cf. e.g., VON*, QMH**)**
- **SAE type and incidence consistent with expectation (cf. e.g., VON*, QMH**)**
- **Most serious events during the first weeks of the study and in smallest babies**

*Rysavy MA et al. JAMA Pediatr. 2020;174: e196294. doi: 10.1001.
**Chee YY et al. Hong Kong Med J. 2017;23: 381-6.

SFT correlates to several clinically meaningful outcomes in premature infants*

Sustained Feeding Tolerance (SFT) Definition

SFT defined strictly as 10 consecutive days with

1. daily enteral feeding ≥120 ml/kg,
2. no parenteral nutrients and
3. average body weight increase of at least 10g/kg/day

Time to SFT is measured from first dose of IP to first day of the first 10-day period and a primary endpoint of the Connection Trial.

*Neu et al, Br J Gastroenterol 2022:4, 255-60

Material and methods - Event correlations to the time to SFT

Event correlations to the time to SFT

Infant material

- 519 infants reaching SFT
- 122 infants not reaching SFT during treatment up to cGA 34w+6 days
- 90 infants were excluded due to early study withdrawal for reasons of death, transfer, withdrawn consent etc

Methods

- Univariable correlation of events to the time to SFT
- Multivariable correlation with use of the Akaike information criterion for events of statistical significance ($p<0.05$) at univariable analysis

Univariable regressions analysis

Events with association of statistical significance (<0.001-0.02) to the time to SFT

Event	Coefficient**	R^2
Birth weight (100 g)	-3.0	8.7
cGA (week)	-2.7	19.4
Apgar score 5 min	-1.0	2.3
Any SAE*	6.8	5.3
GI SAE*	8.5	2.0
Abdominal symptom	3.4	1.6
GI perforation	21	6.4
NEC	6.8	2.6
Clinical sepsis	5.6	3.4
Culture positive sepsis	5.2	2
Days with antibiotics	0.11	4.9

Event	Coefficient**	R^2
Respiratory SAE*	8.0	3.3
Pneumonia	10.1	6.4
BPD	2.4	1.0
Intracranial bleeding	3.8	2.0
PDA	6.2	6.9
Cardiac SAE*	13.6	1.4
Hypotension	14.4	6.5
Renal event	5.9	1.4
ROP	4.9	4.0
Days in hospital	0.25	20.4

*Considered by investigator as e.g. life-threatening
**Coefficients are the number of days difference in time to SFT related to a 1-unit change in the event
***R^2 is the coefficient of determination of the event for the time to SFT

Multivariable regression analysis

Multivariable regression after the stepwise procedure

Event	Coefficient*	P	Event	Coefficient*	P
cGA week	-0.74	0.04	Respiratory SAE	4.5	0.01
Abdominal symptom	2.5	0.02	Pneumonia	4.2	0.009
GI perforation	15.4	<0.001	Cardiac SAE	9.0	0.04
Clinical sepsis	3.5	0.003	Hypotension	5.7	0.009
Days on antibiotics	0.04	0.03	Days in hospital	0.1	0.001

Model overall R^2, 35%

*Coefficients refers to the number of days difference in the time to SFT for a 1-unit change in the event

Conclusions

Event correlations to the time to SFT

- Several GI complications associate to a delay in the time to SFT.
  - stronger for perforation and obstruction than NEC.
- The time to SFT is extended in infants with extra-GI complications like pneumonia, cardiac events and hypotension .
- Co-occurrence of events (as measured with univariable analyses) prolong the time to SFT even further.
- Reasons for withholding enteral feedings in ELBW infants may benefit from re-evaluation.

Thank you & Arrivederci

Infant Bacterial Therapeutics AB

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