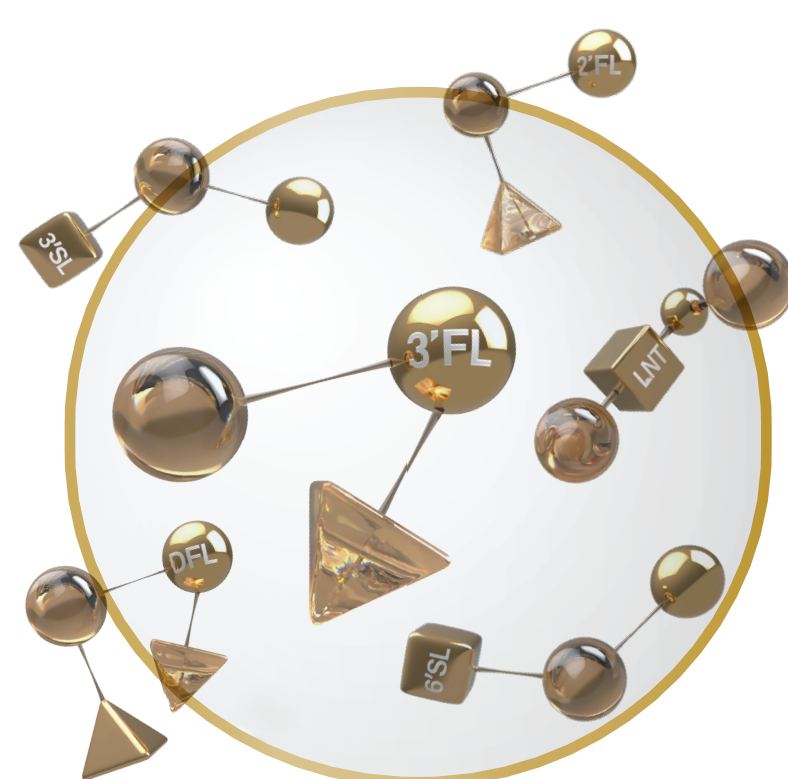




CLINICAL EVIDENCE SUMMARY

First evidence of infant formula with a specific age-adapted blend of 6 HMOs, *B. infantis* and *B. lactis*^{1,2}



2'FL, 3FL, DFL,
6'SL, 3'SL, LNT



B. longum subsp. infantis
(LMG11588)



B. lactis (CNCM I-3446)

Design & objective:

Randomised, controlled, double-blind trial to demonstrate the effects of formula containing a blend of 6 HMOs* and 2 probiotics on infant growth and gut microbiome

Population

Healthy infants ≤ 14 days old, randomized to receive Control Formula (CF, n=117) or Experimental Formula (EF, n=119)

Breastfed infants (BF, n=82) enrolled as a non-randomised reference group

Primary endpoint

Weight gain velocity (g/day) in the EF vs. CF group, measured from baseline to 4 months

Secondary endpoints

Microbiome profile, tolerance and stooling patterns in the EF vs. CF at 3 months

RESULTS OF THE STAGED ANALYSIS**

PRIMARY ENDPOINT



Non-inferior weight gain velocity in EF vs. CF group at 4 months

- ➔ Demonstrating healthy age-appropriate growth similar to CF and BF groups

SECONDARY ENDPOINTS



Microbiome profile and gut environment in the EF vs. CF group at 3 months

- ➔ Significantly higher beneficial bifidobacteria 44.7% vs. control 34.1% (p<0.05)
- ➔ Reduced prevalence of potentially pathogenic bacteria *C. difficile* (reducing the risk of GI infections)

Supporting a favourable GI tolerance and normal stooling pattern

- ➔ Good GI tolerance of EF formula - no significant differences in IGSQ scores amongst groups
- ➔ Normal stooling patterns with no significant differences between formula-fed groups

*Structurally identical Human Milk Oligosaccharides, not sourced from breast milk; **This ongoing clinical trial was designed with a staged endpoint analysis (from enrollment until 4 months); GI: gastro-intestinal.

1. Picaud JC, et al. Abstract prepared for the 15th Excellence in Pediatrics Conference, 30.11 – 2.12, 2023.

2. Miranda, et al. Abstract prepared for the 15th Excellence in Pediatrics Conference, 30.11 - 2.12, 2023.

Clinical trial is ongoing,
with follow-up until 15 months of age

Conclusion

Formula supplemented with an age-adapted blend of 6HMOs, *B. infantis* and *B. lactis*:

- ✔ is safe, well tolerated
- ✔ supports age-appropriate growth
- ✔ positively supports gut environment by increasing beneficial bifidobacteria and decreasing *C. difficile*, a potential pathogenic bacteria, which may reduce the risk of GI infection