LPCN 1107

Pioneering A Solution to the Preterm Birth Health Crisis

LIPOCINE®
ENHANCING HEALTH

Preterm Birth (PTB) - A Significant Global Public Health Issue

High Unmet Medical Need with No Effective Treatment

- Every year, ca **15 million babies** are born preterm worldwide
- Globally, the rate of PTB ranges from **5% to 18%** of babies born
- In the US, **10%** of all pregnancies, ca 1 PTB every minute
- **Main cause of perinatal mortality and morbidity** in most countries: **75%** of perinatal mortality, **>50%** of long-term morbidity associated with poor perinatal outcomes; ca 1 million children younger than 5 years die each year due to PTB complications
- ≥ $25 billion economic impact (US, 2016)
- **Medical costs** for PTB infants are ca 10x higher than for full term infants; average **length of inpatient stay** ca 9x longer for a preterm newborn (13 days) vs a baby born at term (1.5 days)

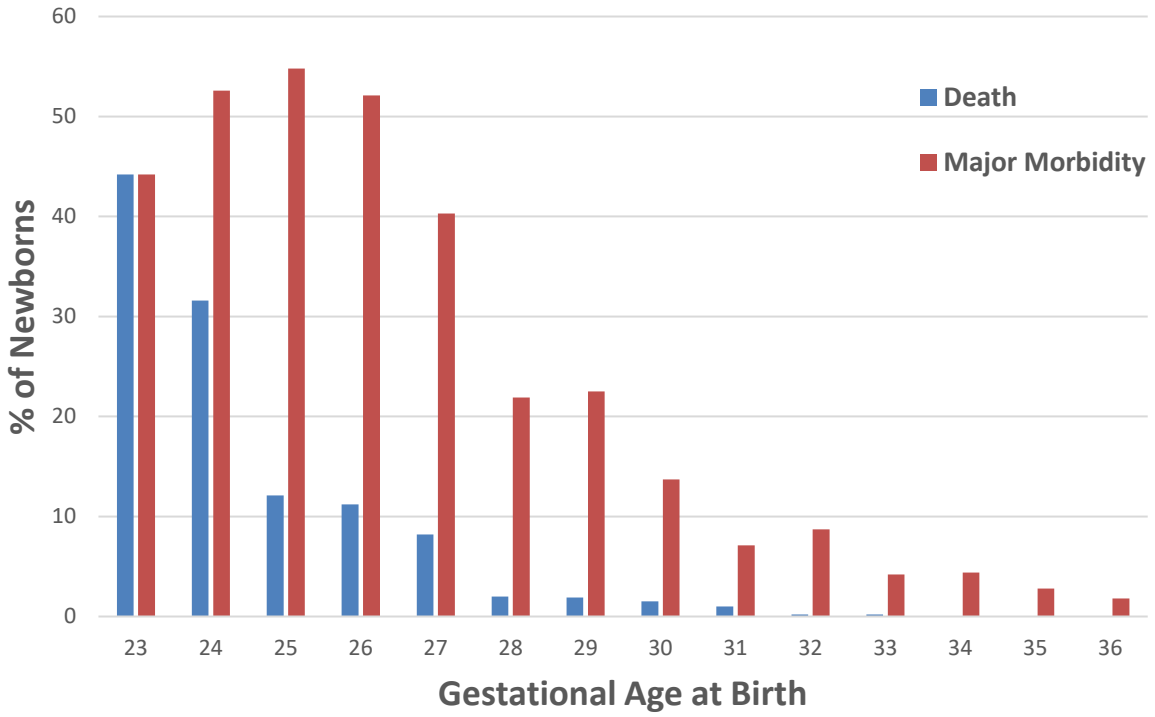
LIPOCINE® ENHANCING HEALTH

Source: National Vital Statistics Reports, Vol 67, No. 8, 2018; Centers for Disease Control and Prevention, 2017; World Health Organization, Born too soon: The global action report on preterm birth, 2012; World Health Organization, Preterm Birth, 2022

Infant Mortality/Morbidity Related to Gestational Age

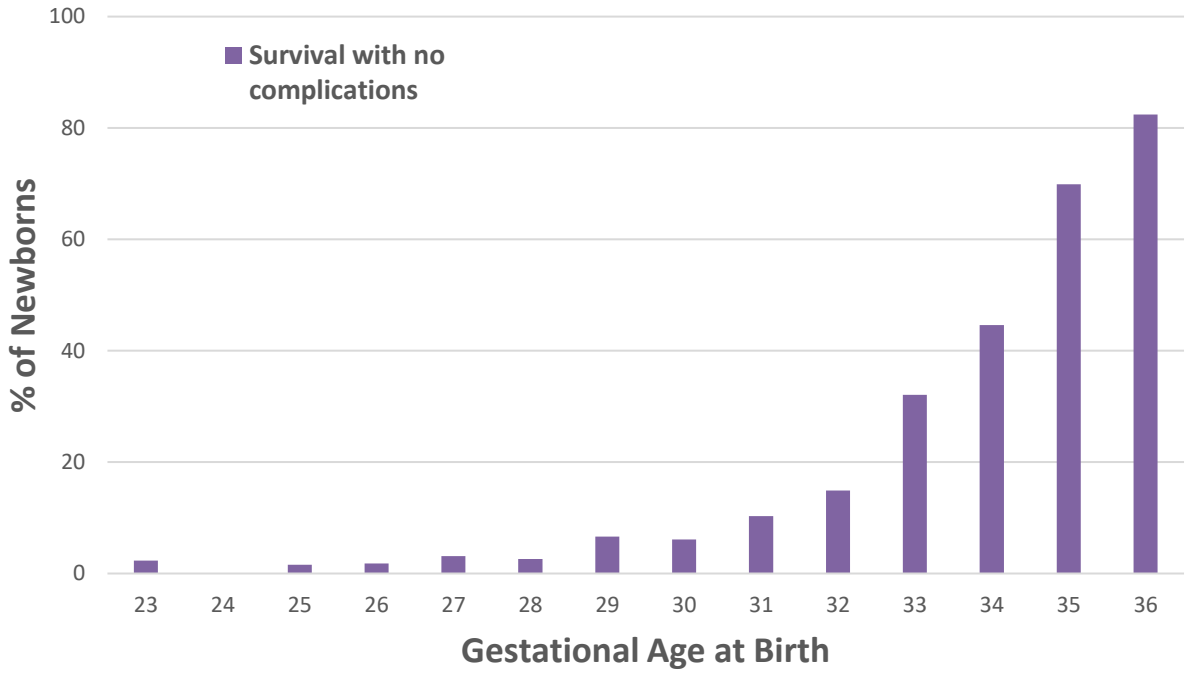
Benefit of Prolonging Gestation Age

Mortality and Major Morbidity



- Major morbidity includes persistent pulmonary hypertension, intraventricular hemorrhage grade 3/4, seizures, hypoxic-ischemic encephalopathy, necrotizing enterocolitis stage II/III, bronchopulmonary dysplasia

Survival with No Complications*



*No major or minor morbidities

- Minor morbidity includes intraventricular hemorrhage grade 1/2, necrotizing enterocolitis stage 1, RDS, hyperbilirubinemia requiring treatment, hypotension requiring treatment

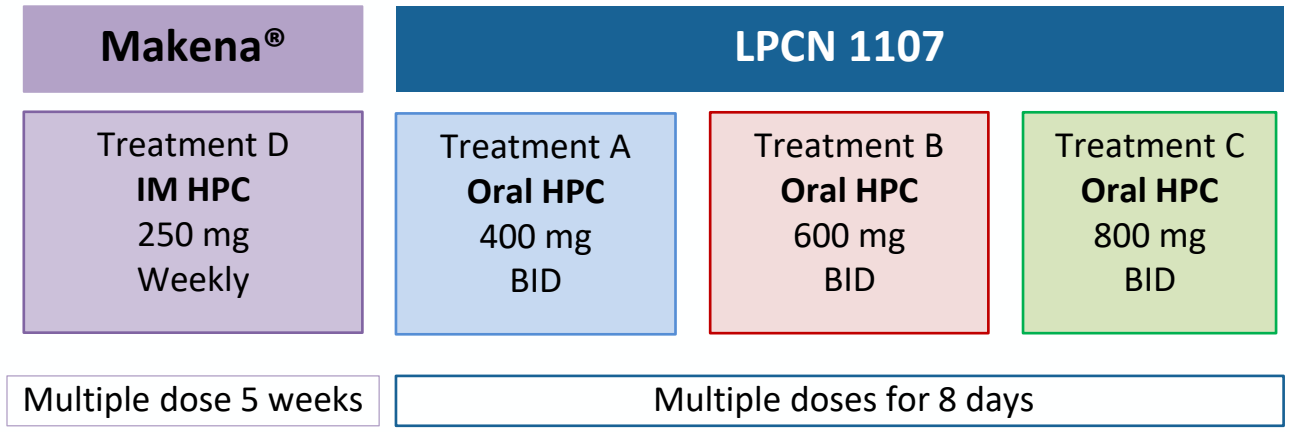
LIPOCINE® ENHANCING HEALTH

Source: Manuck et al., AJOG, 215(1):103.e1-103.e14, 2016

Dose Finding Study Design

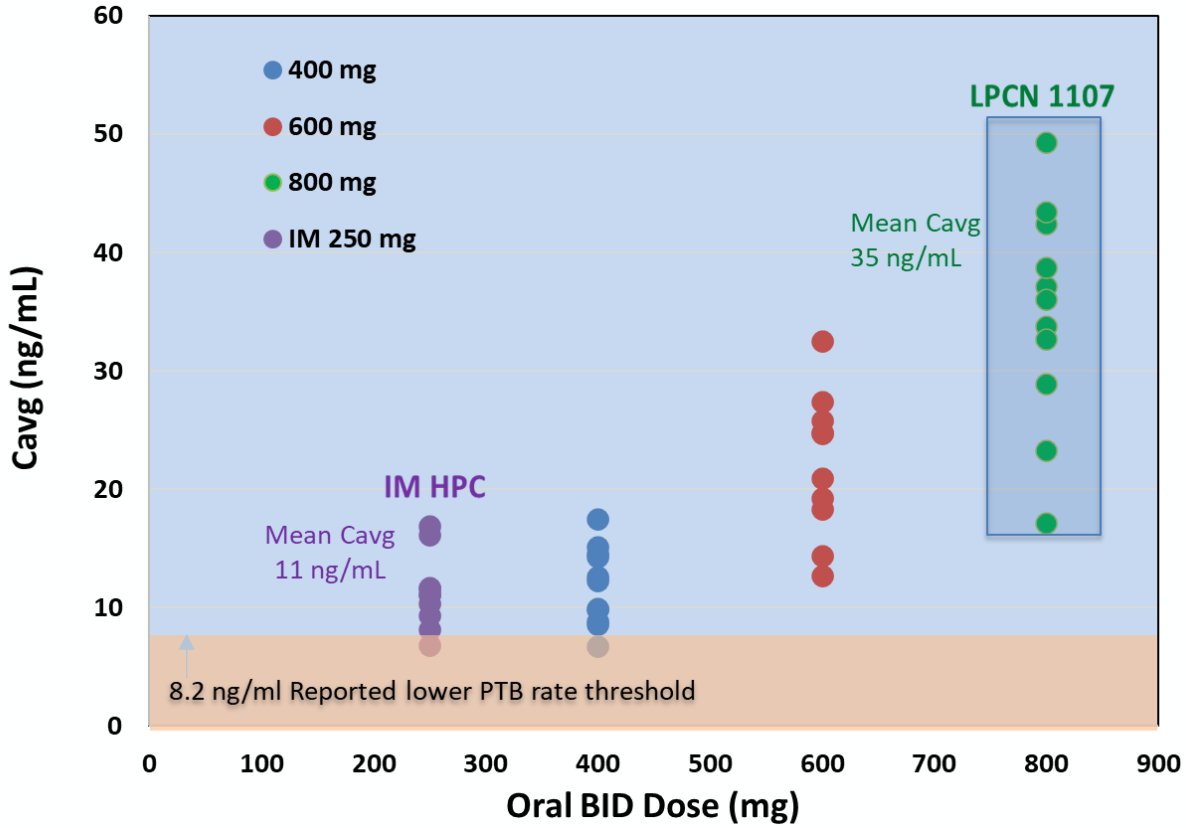
To find dosing regimen that above reported lower PTB rate threshold (8.2 ng/mL)

- Open-label, four period, four treatment study
- 12 healthy pregnant women
  - Age of 18-35 years: Screened at gestation age in 16-18 weeks
- Periods
  - Period 1 to 3 (Oral dose)
    - ✓ Day 1: Single dose – PK sampling for 24 hours
    - ✓ Day 2 to 7: Two doses daily (approximately 12 hours apart)
    - ✓ Day 8: Two doses 12 hours apart- PK sampling for 36 hours
  - Period 4 (IM Injection dose)
    - ✓ Week 1 to 5: Once weekly IM, Makena®: PK sampling in Week 5 for one week

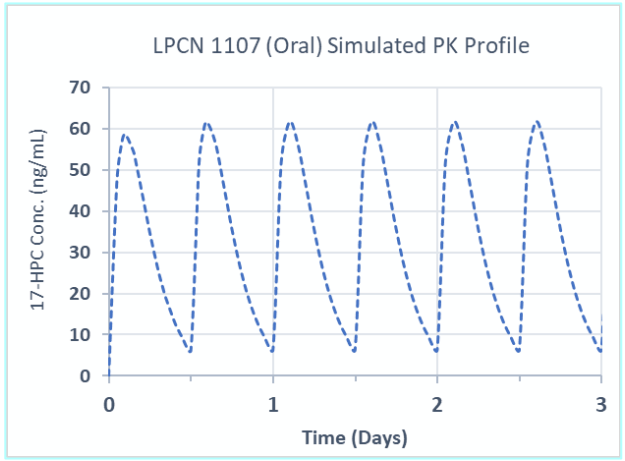


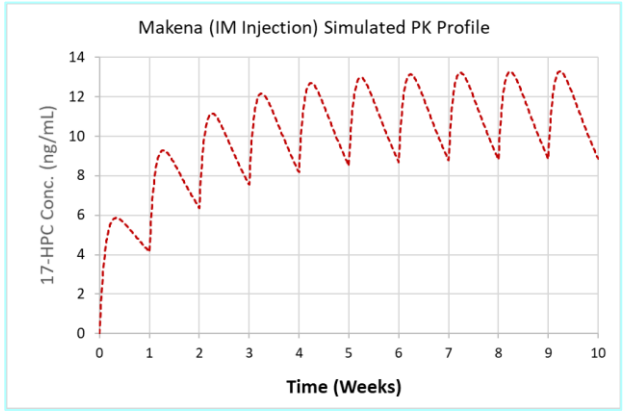
Comparative Steady State PK profiles* to Injectable HPC

Dosing Regimen Ensures ALL Patients Above Reported Lower PTB Rate Threshold



*PK results obtained from post 35 days for weekly IM Injection & post 8 days of BID dosing for oral from the dose finding study

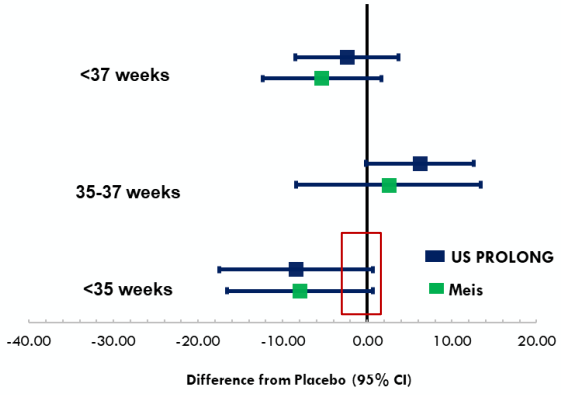


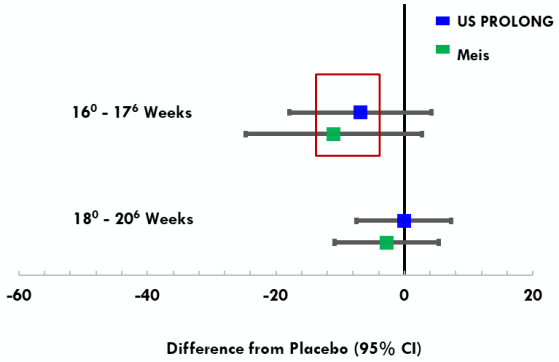


Achieve <u>Higher</u> Target Blood Levels <u>Sooner</u>

Success Focused Clinical Design Scenario

Summary



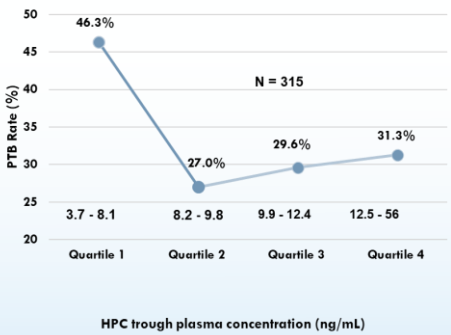


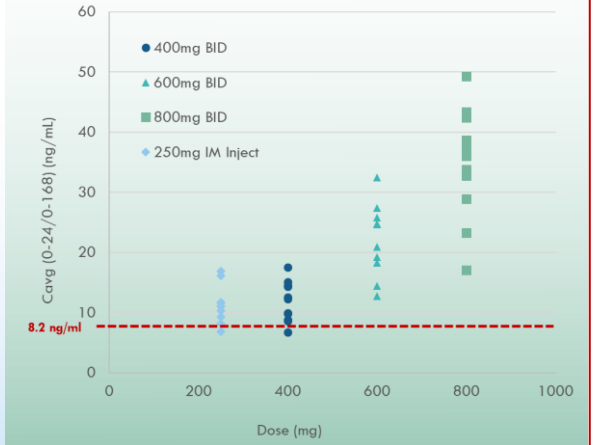
Immediately prior QD

Levels: minimizing subjects below the efficacy threshold

Early Therapy Initiation

GAQD < 35 wks. with >50% population with GAQD <32 wks.





LPCN 1107 – “Phase 3 Ready” Partnering Opportunity

Potential to be the Only Product Approved for Preterm Birth (PTB) On the Market

>$1B US Market Potential

Strong pharmaco-economic justification

Oral, a Major Contribution to Patient Care

Self administration

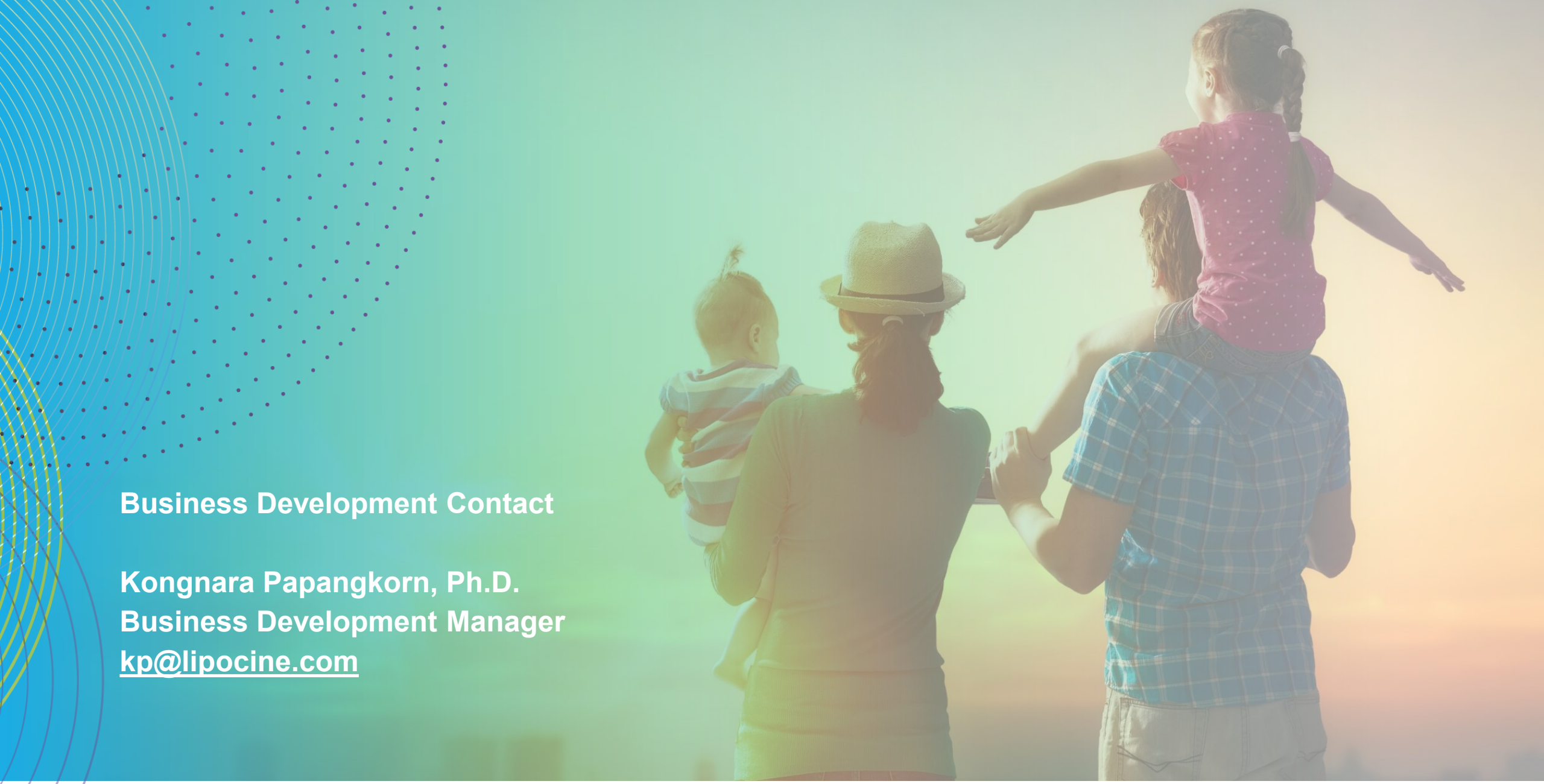
No injection site reactions

Accelerated Approval Pathway

Compelling efficacy rationale

Orphan Drug Designation

Broad IP Coverage



Business Development Contact

Kongnara Papangkorn, Ph.D.
Business Development Manager
kp@lipocine.com

LIPOCINE®
ENHANCING HEALTH