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ENHANCING HEALTH

LPCN 1107

Pioneering A Convenient Solution to the Preterm Birth Health Crisis

Non-Confidential

Pioneering a Patient Preferred Solution to the PTB Health Crisis

Overview of the Partnering Opportunity

- ✓ *LPCN-1107 is a **late-stage "de-risked" blockbuster women's health** opportunity that addresses an urgent medical need*
- ✓ *Preterm birth ("PTB") is a health crisis in the US and globally, and is estimated to **cost the US healthcare system >$25B annually****
- ✓ *LPCN-1107 is poised to **be the leading FDA approved product** to reduce the risk of preterm birth, with no near-term competition*
- ✓ *Eligible for **accelerated approval with potential for a single pivotal study**, the design of which is informed by an end-of-phase 2 meeting with the FDA and recent regulatory analysis of clinical data with an injectable HPC product*
- ✓ *Product development, including pivotal study design, is endorsed by prominent KOLs and **the MFMU Network***
- ✓ *Lip'ral drug delivery technology enabled the **first oral delivery of HPC, which overcame a significant decades-long technical challenge***
- ✓ *LPCN-1107 has been granted **Orphan Drug Designation status** by FDA and is further protected by a robust **patent portfolio with term lasting until 2041/2042 (US/Ex-US)***
- ✓ ***Global registration and life cycle management** of LPCN-1107 represents a significant expansion opportunity*

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** Pediatric Research 60, 775–776, 2006*

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)

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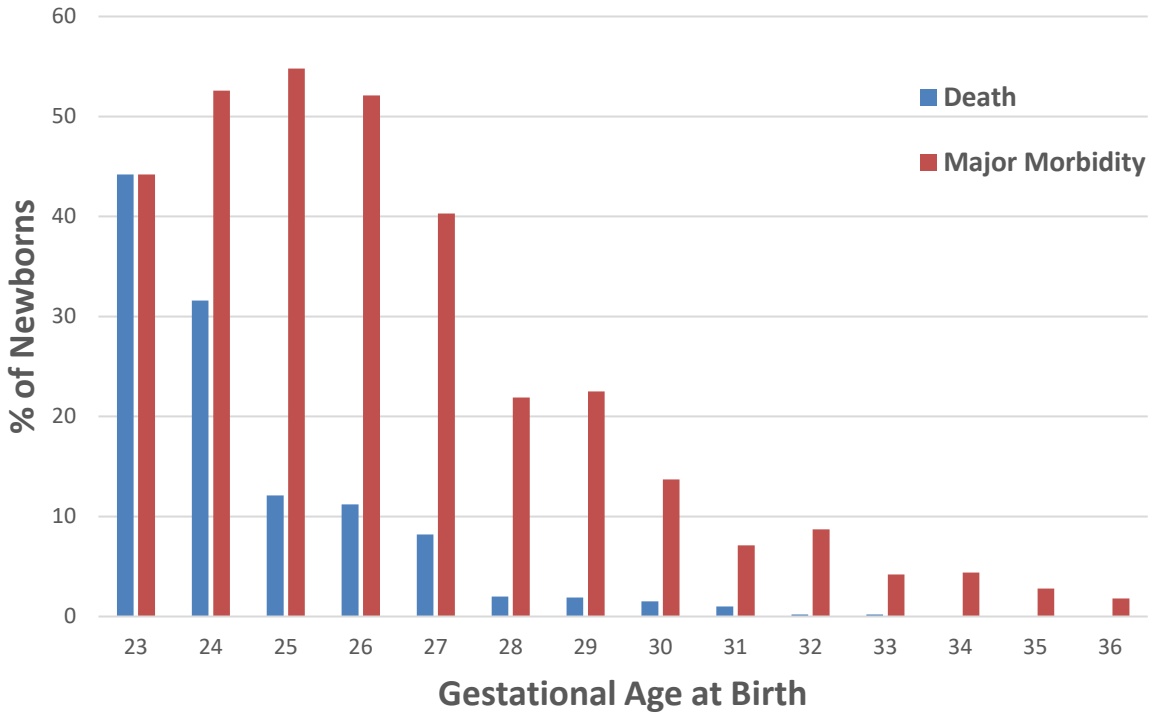
Source: National Vital Statistics Reports, Vol 67, No. 8, 2018; Centers for Disease Control and Prevention, 2017; World Health Organization, Born too soon: The global action report on preterm birth, 2012; World Health Organization, Preterm Birth, 2022

Infant Mortality/Morbidity Related to Gestational Age

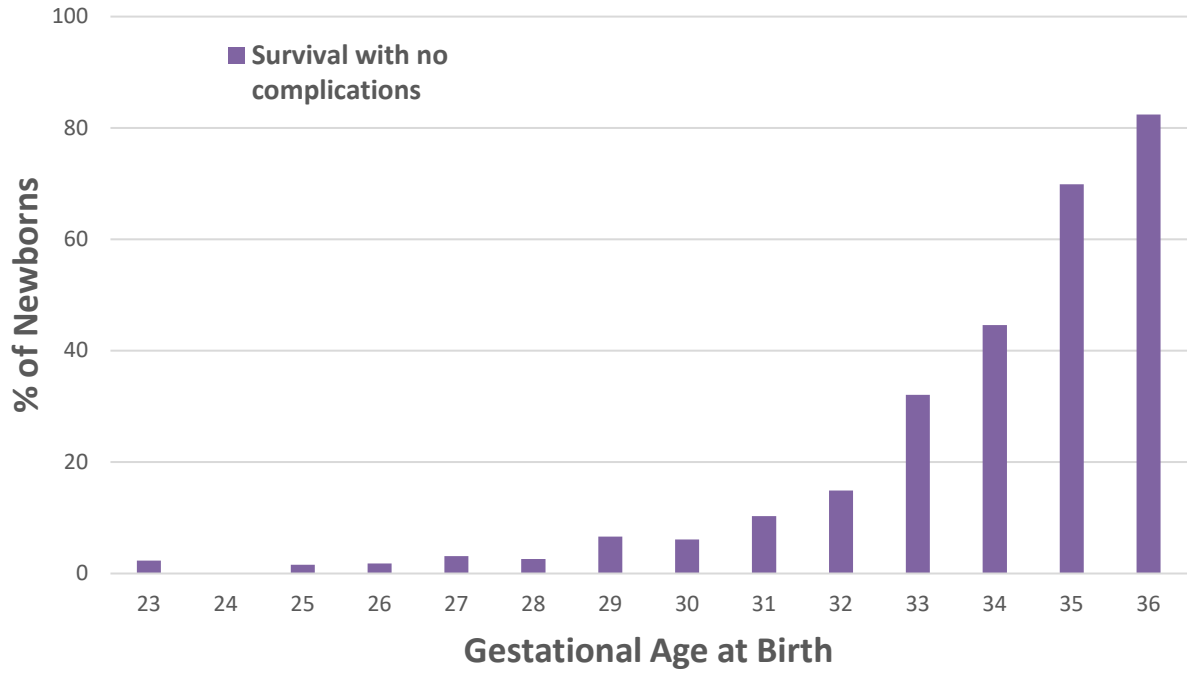
Benefit of Prolonging Gestation Age

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

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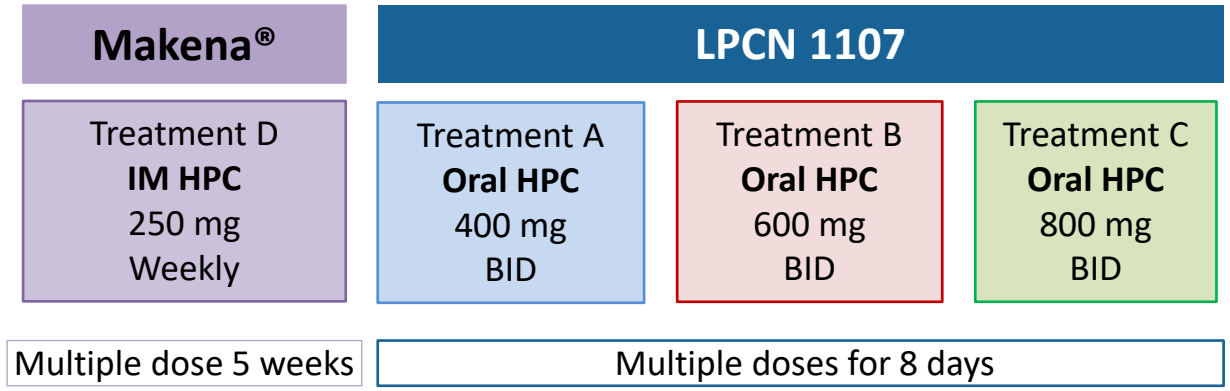
Source: Manuck et al., AJOG, 215(1):103.e1-103.e14, 2016

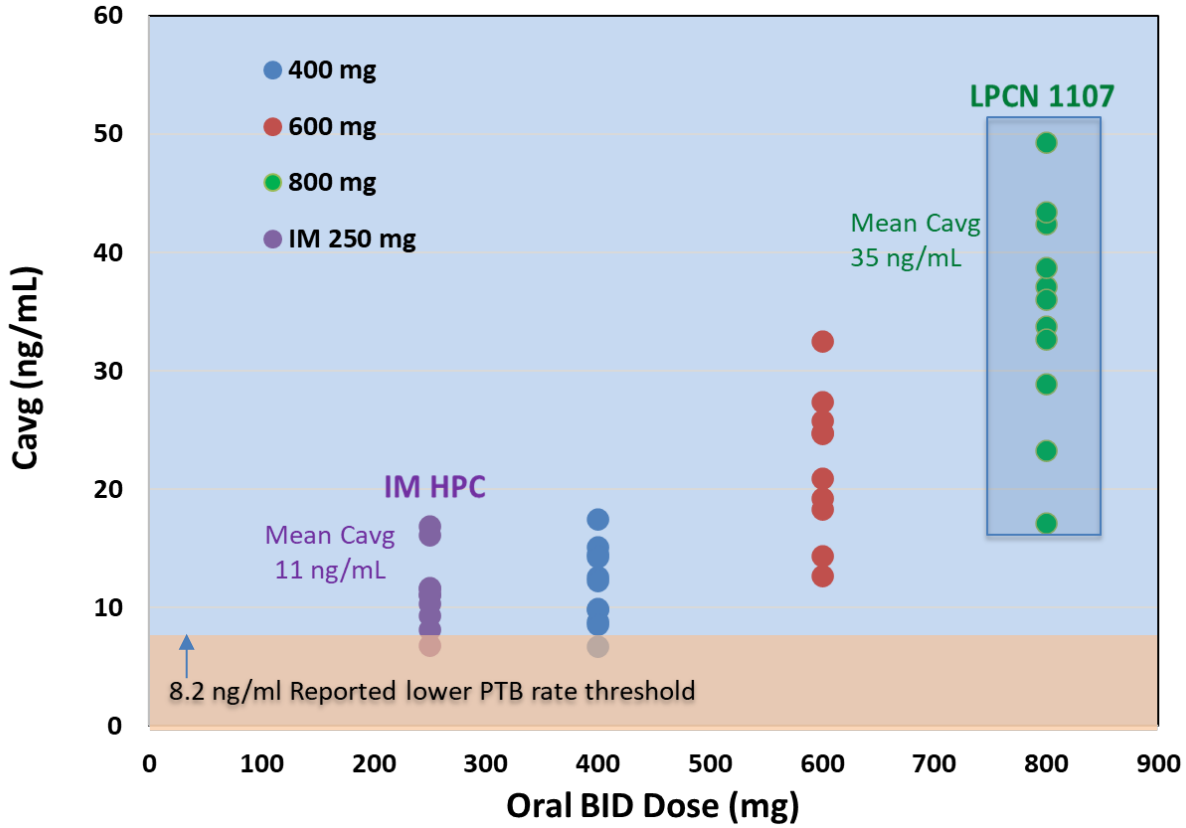
Dose Finding Study Design

- 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
- Treatments

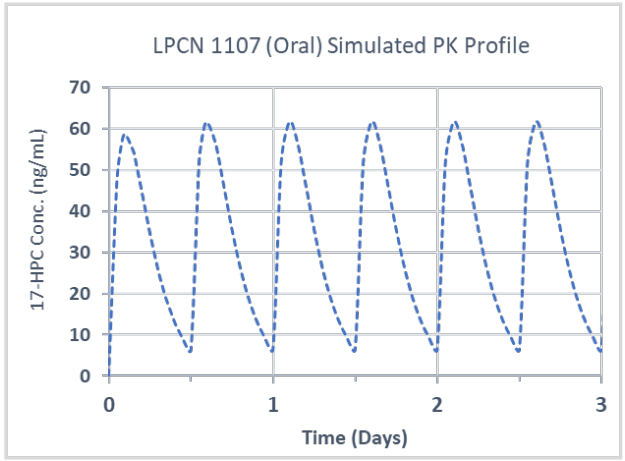


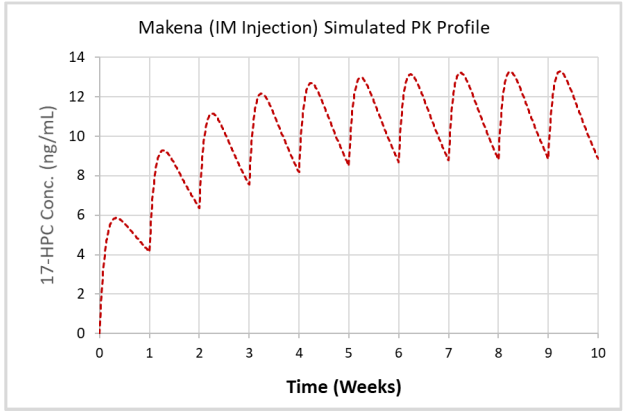
Comparative Steady State PK profiles* to Injectable HPC

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 Higher Target Blood Levels Sooner

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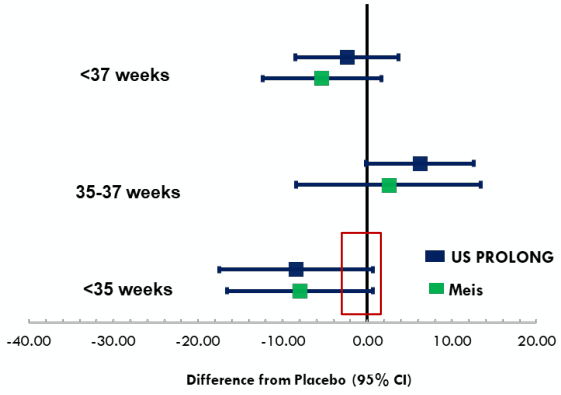
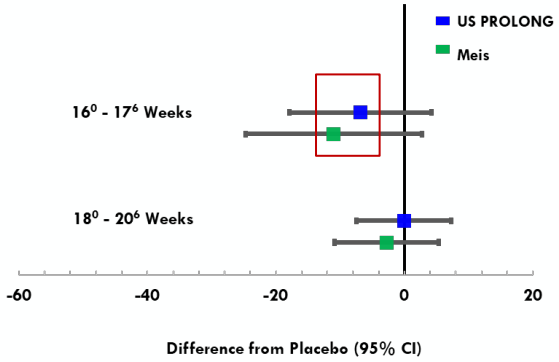
Success Focused Clinical Design Scenario

Summary



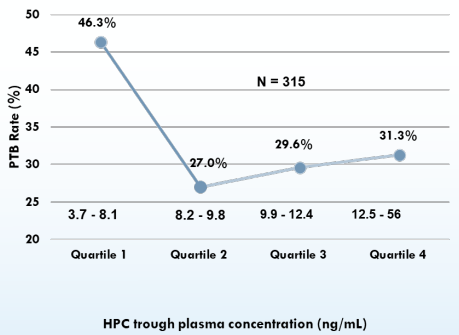


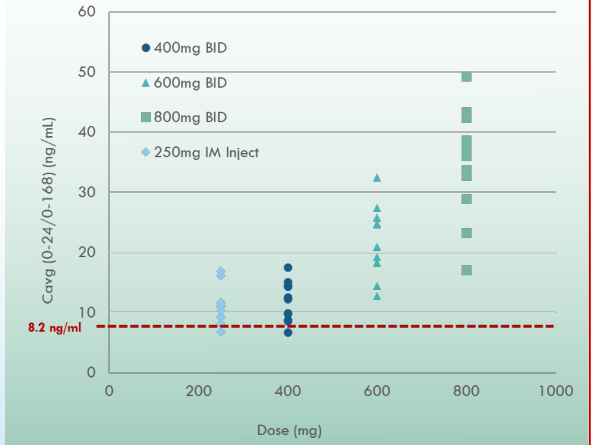
Immediately prior QD

Levels: minimizing subjects below the efficacy threshold

Early Therapy Initiation

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





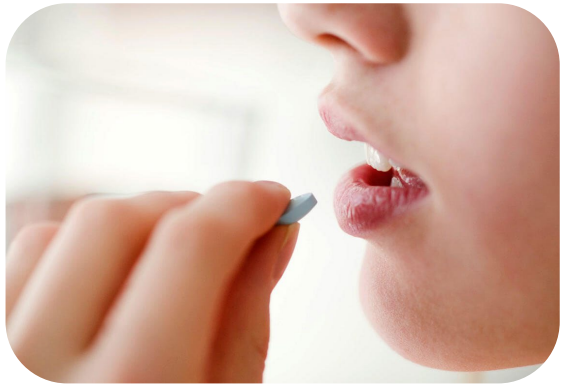
LPCN 1107 – “Phase 3 Ready” Partnering Opportunity

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

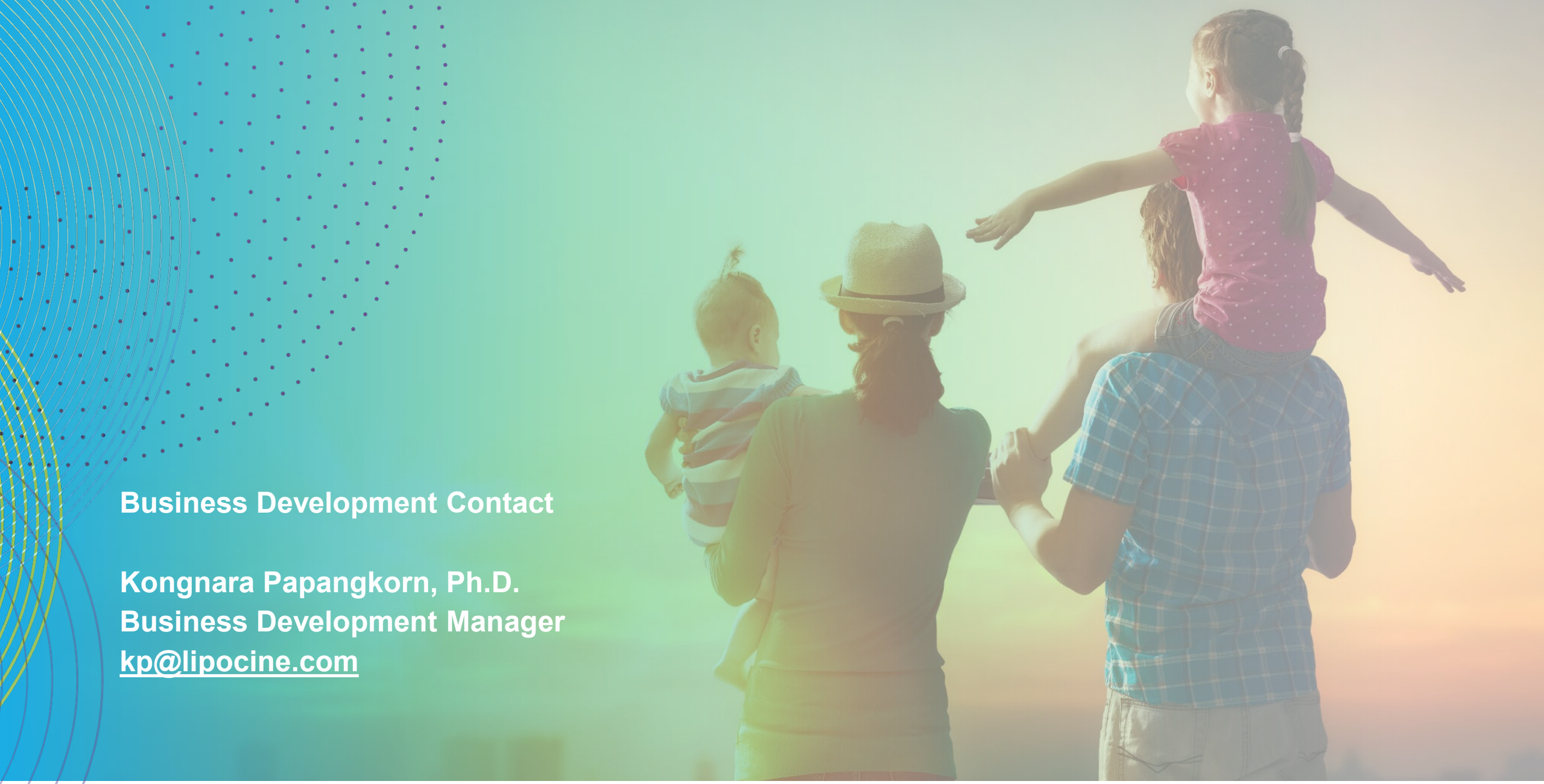
No injection site reactions

Accelerated Approval Pathway

Compelling efficacy rationale

Orphan Drug Designation

Broad IP Coverage



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