



## **In Situ Forming Depots Provide Long-Acting Therapy From a Single Injection**





CMC Pharma

# Drug Product Development Services

- **Assisting Commercial Clients & Government Agencies Since 2014**
  - Services offered from pre-clinical through post approval
  - Experienced staff: most employees decades industry experience
  - Injectables, tablets, capsules, and long-acting formulations
- **Services Include:**
  - cGMP lab services
  - Pre-formulation studies
  - Formulation development
  - Analytical development & validation
  - Stability & compatibility studies
  - Drug delivery system design
  - Prototype preparation
  - Process Development & Tech Transfer





CMC Pharma

# Our Approach to Drug Delivery

- Evaluates multiple technologies for drug delivery applications:
  - *in situ* forming polymers
  - Drug particle suspensions
  - Consider multiple manufacturing processes
- Develops injectable long-acting drug delivery from several days to several months
  - Focus on *in situ* gelling technologies
    - PLGA family of polymers
    - Sucrose acetate isobutyrate (SAIB)
- Routinely formulates PLGA and other polymer implants & formulations for controlled release drug delivery applications.





# *In Situ* Forming Gel Implants





# In Situ Forming Depots Provide Long-Acting Therapy From a Single Injection

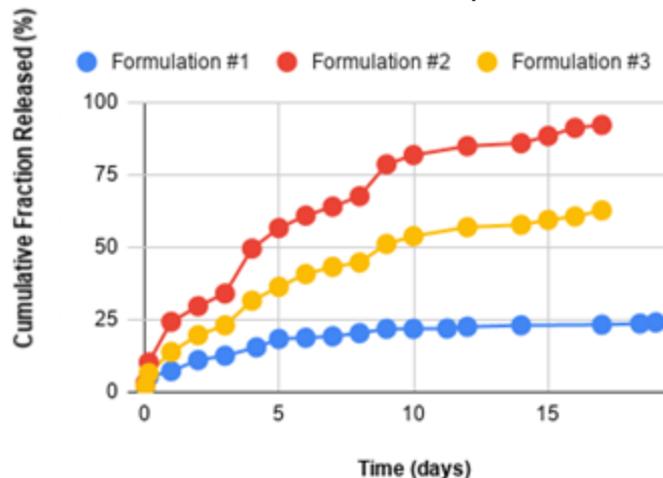
- Injectable formulation technology with low cost-of-goods
  - Simple Manufacturing process
- Core technology is off patent (currently non-proprietary)
  - Opportunity to create IP for API or indication specific Drug Products
- The formulation technology and excipients are utilized in existing FDA-approved products
  - Products that are approved for a range of clinical indications (e.g. pain management, mental health, hormonal treatments)



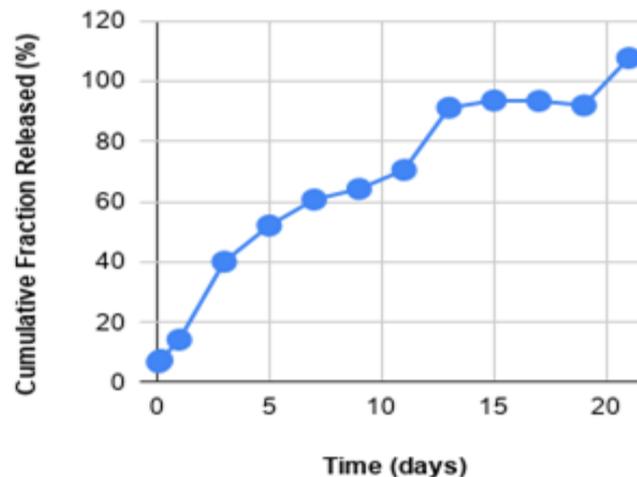


# In Vitro Release from SAIB & PLGA in situ depots

SAIB in situ depots



PLGA in situ depots



Formulation parameters can be adjusted to optimize release rates and duration, and include: SAIB/PGLA concentrations, API particle size, solvent selection, manufacturing process, etc





# Injectable Formulation Technology with Low Cost-of-Goods

- Straight-forward manufacturing unit operations results in low COGs
  - Compounding: Mixing three primary components
  - Filling: Utilize standard filling lines and container closures (e.g., vials, stoppers, seal)
  - Sterilization: Terminal sterilization by gamma or e-beam irradiation





# Opportunity to create IP, API, or Indication Specific Drug Products

- In situ forming gels have been investigated for 30+ years
- Core patents filed in 1990s are now expired
- However, formulation or indication specific patents are possible





# Approved Products (In Situ Gels)

Product	Drug	Biodegradable Controlled Release Excipient	Duration (Month)	Innovator
Perseris	Risperidone	PLGA	1 month	Indivior
Sublocade	Buprenorphine	PLGA	1 month	Indivior
Eligard, Fensolvi	Leuprolide	PLGA	1, 3, 4, or 6 month	Tolmar
Zynrelef	Bupivacaine, Meloxicam	tri(ethylene glycol) poly(orthoester)	3 days	Heron
Posimer	Bupivacaine	SAIB	3 days	Durect



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