

Oxytocin in Uniject – December 2006 Update

Activities in Argentina and India



Commercialization Definition

“...the process undertaken by the producer (whether public or private) to evaluate, develop, register with appropriate national Drug Regulatory Authorities (DRAs), and then sell either drug or vaccine in Uniject.

Oxytocin-Uniject will be considered “commercialized” or “commercially available” in a country when that country’s DRA grants the pharmaceutical producer permission (e.g., registration) to sell and promote oxytocin-Uniject.”



Oxytocin in Uniject: 2006 Progress with BIOL of Argentina

Brief History:

- Stuck in this loop up through April 2005!
- Moved into focused development collaboration with BIOL in Spring 2005
- Stability study initiation delayed until March 2006

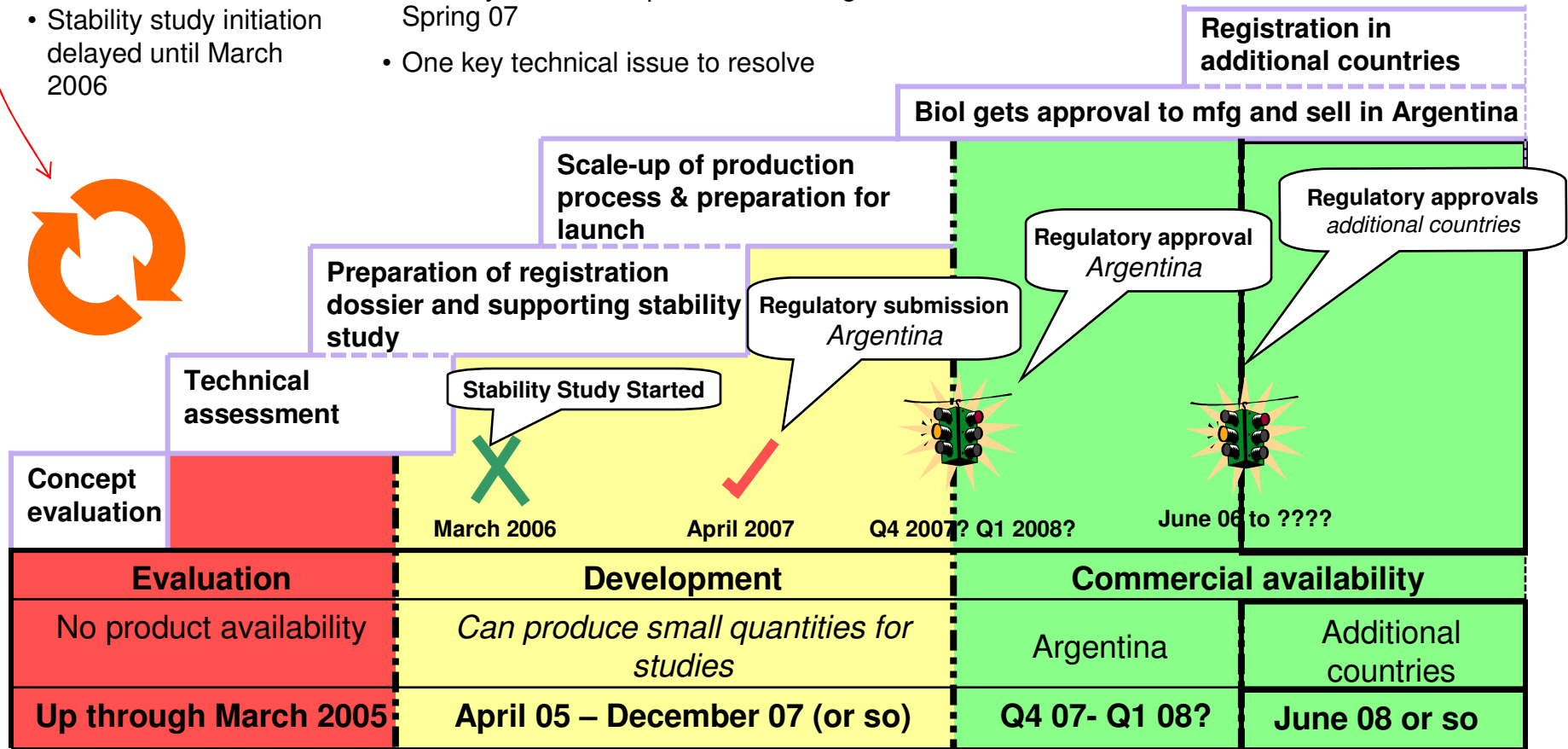


Current Status:

- 6 months of stability study completed October 06 with positive results
 - Excellent stability at 2 – 8* c
 - Potential stability at 25* c
- Production to support Mali project in January 07, second production during Spring 07
- One key technical issue to resolve

Key Next Steps:

- Resolve technical issue of extractables
- Produce & deliver for Mali and Argentina
- 12 month stability data
- BIOL registration dossier submission



Gland Pharma of India Progress in 2006

- Completed compatibility study with positive results
- Delayed in starting formal stability study due to equipment unavailability
- Plan to initiate stability study in Q1 07
- May be able to register product in India by end of 2007
- Will not have full international dossier until mid 2008



Field Use Plans

- Mali in 2007 (POPPHI and Partners)
- Argentina in 2007 (POPPHI and Tulane)
- India 2007 or 2008 (ICMR)
- South Africa 2007 or 2008 (PATH)
- Likely more as product becomes available



Potential Supply to UN Agencies (UNFPA, UNICEF, etc)

- Each producer must be evaluated for quality before being offered opportunity to sell to UN agencies
- This vendor qualification process is product (Uniject/Oxytocin) and producer specific
- **BIOL and/or Gland Pharma can not request UN agency vendor qualification for Oxytocin/Uniject until after they have home country FDA approval**
- Realistic scenario—UN vendor qualification process during 2008, potential sales to UN agencies begin in 2009



Oxytocin/Uniject Summary

- Progress toward commercial availability, but with delay
- Will supply for field use in 2007
- Argentine and Indian FDA registration possible (but not guaranteed) end of 2007
- Commercial availability in 2008
- Commercial sales to UN agencies unlikely before 2009



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