GP Pharm

Innovative Drug Delivery Systems in Urology and Oncology
GP Pharm is a Spanish biopharmaceutical company, founded in 2000 and located in Gavà (Barcelona – Spain).

The company is specialized in research, development, manufacturing and marketing of products for injection within Oncology and Urology fields, based in own innovative drug delivery systems.

These technological platforms include Microspheres and Liposomes.

The company works in the complete development of these drugs, from the preclinical studies until the launch to the market.

GP Pharm is commercially international oriented, supplying its products through either owned net sales forces or strong alliances with partners.

The company doubled its turn-over in 2010 and reached in 2011: 13,6M€, maintaining its constant investment in R&D.

The company has currently 100 employees from which more than 50% are high qualified: either PhDs or Bachelor Degrees.
GP Pharm Activities

**R&D Projects**
- GP Pharm develops Drug Delivery formulations for injection for its own and for third parties, applied to Oncology CNS and CVS.

**Contract Manufacturing**
- GP Pharm is able to produce cyto-toxics and hormonal products in drug delivery platforms for its own and also for third parties, although is mainly interested in NCE or added value products.

**Licensing In & Out**
- GP Pharm would like to expand its international presence through well established pharmaceutical companies, in order to promote and distribute its portfolio products with licensing and supply agreement. Also is looking for potential partners to co-develop its clinical projects in advanced stage.

**Commercialization**
- GP Pharm has its own commercial structure in Spain and Portugal, and is building up subsidiaries in South Europe countries and South America. Its commercial world wide strategy is based on licensing, joint ventures and distribution agreements.
Drug Delivery Platforms: Microspheres

Microspheres for sustained release. **POLITRATE®.**

- GP Pharm has experience obtaining Microspheres through out different technologies such as: **double emulsion** and **coacervation**.

- Patented Triethyl Citrate and PLGA Polimer Microspheres.

- Ability to control release from 5-6 days up to 6 months.

- Use of Triethyl Citrate in different ratios within the capsule surface allows to encapsulate virtually any water soluble molecule.

- Non patent infringing, European and US patents for the system have already been awarded.

- Enhanced control during release phase.

- Enhanced sustained release during the whole treatment.

- Enhanced pharmacologic effect.

- Decrease of the requested dose per administration unit.
GP Pharm has expertise using different composition of lipid components for Liposome preparation: cationic, anionic, neutral (being used separately or in different ratios).

Also expertise obtaining Liposomes through out different sizing technologies such as: **microfluidification**, **extrussion** and **sonication**.

Drug substance included in the wall of the liposome.

Presence of lipochromann an antioxidant product in the wall of the liposome.

Reduced drug substance degradation process.

**Drug Delivery Platforms: Liposomes**

- Sarcodoxome®: Designation as Orphan Drug. EMEA and FDA, phase II study.
  (Liposome Doxorubicin)

**Target Liposomes**: Under development
Product Portfolio (I)

Microspheres formulations

<table>
<thead>
<tr>
<th>Product</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Registration</th>
<th>Marketing</th>
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<tbody>
<tr>
<td>Lutrate® Depot (Leuprolide 1 month)</td>
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<td>Lutrate® Depot (Leuprolide 3 months)</td>
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<td>Lutrate® Depot (Leuprolide 6 months)</td>
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<td>Risperidone Depot (Risperdal Consta)</td>
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<td>Octreotide Depot</td>
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<td>Minoctre® (Octreotide MAR)</td>
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2nd Generation, LHRH and other hormones
**Liposomal formulations**

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<tr>
<th></th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Registration</th>
<th>Marketing</th>
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<tbody>
<tr>
<td>Sarcodoxome ® (Liposomal Doxorubicin)</td>
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<td>Orphan drug status</td>
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**2nd Generation Cytotoxics**

**Target Liposomes**

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<th>Preclinical</th>
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<th>Phase II</th>
<th>Phase III</th>
<th>Registration</th>
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<tbody>
<tr>
<td>Doxorubicin</td>
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<td>Irinotecan</td>
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<td>Gemcitabine</td>
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**3rd Generation, targeting Cytotoxic Delivery**
## Product Portfolio (III)

### Hormonal products

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<tr>
<th></th>
<th>Pharmaceutical development</th>
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<td>Octreotide</td>
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<td>Somatostatin</td>
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<tr>
<td>Nictur TM (Desmopressin oral drops)</td>
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## Product Portfolio (IV)

### Generic Cytotoxics for Injection

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<tr>
<td>Gemcitabine</td>
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*Some future projects:*
- PEG Liposomal Doxorubicin (Caelyx)
- Pemetrexed (Alimta)
The GP Pharm’s production facility is located in Sant Quintí de Mediona (at about 75 Km from Barcelona) and in a 35,000 square meters area.

The plant consists on 6 isolated buildings and 3 of them are exclusively dedicated to production.

1. Office and Laboratory
2. Warehouse
3. Services
4. Cyto-toxic Drugs
5. High Active Drugs
6. Drug Delivery
Approvals and Certifications

- GMP approved facilities by EMEA (European), TGA (Australian) and PMDA (Japanese) Authorities

Recently, also approved in Gulf Countries, Canada and Turkey
Which products?

- Sterile drug products for injection of:
  - Finished dosage forms with indications for the **treatment of cancer** (cyto-toxics).
  - Finished dosage forms of **high potency** drug substances (hormonal).
  - **Drug delivery systems**: microspheres and liposomes.

Which dosage forms?

- Vials.
- Ampoules.
- Pre-filled syringes.

Which formulations?

- Liquid.
- Freeze dried.
Contract Manufacturing Services

- GP Pharm is allowed to manufacture investigational medicinal product.
- Facilities has achieved requirements on annex 13 of eGMP.
- Hence our facilities are specially authorized to manufacture products on clinical development.
Providing good manufacturing items from the beginning

- Cold-storage rooms, either for stability studies of storage of finished.
- Segregated areas for quarantine, approving and rejection of samples.
- Sampling area.
- Water for pharmaceutical use: purified water (WFI and pure steam are produced in independent loops in each plant to avoid cross contamination).
- Industrial steam and return of condensers.
- Sanitary cold water.
- Sanitary hot water.
- Compressed air.
- Technical gases.
- Natural gas.
Thank you for your attention
visit us at www.gp-pharm.com

See you at the CPhI 2012 (Booth 9H06)