MedPointe Product & Process Development
Program Priorities & Issues
November 18, 2002

COMMERCIAL PRODUCT TECHNICAL SUPPORT

ASTELIN NASAL SPRAY

Issue/Program	Priority	Critical Path	Timing	Manager[1]	Status/Commer
Qualify 34.5 mL V-bottom bottle	High	Launch of V-Bottom Bottle	Q4/FY03	JH/ADD/ CY	Task Force assembled to invest implementation by Spring 03. Additional data from Regulator reviewed and summarized.
Qualify Marlex 5502BN Resin Stability program	High	Maintain Component Supply	Q3/FY03	CY/ML	Studies initiated to qualify trans Additional samples (4.5 month) particulate testing. Results are The additional data is needed t analysis.
Valois VP3 Pump – Exclusive Supply Contract	Medium	Brand Protection		ADD	Discuss exclusive pump sales a limit potential use by future ge date 11/15/02 at request of Sa

DORAL TABLETS

Qualify Decatur to manufacture Doral Tablets	High	Maintain Commercial Tablet Supply	Q4/FY03	VP/GD	Inter-departmental review of M in recommendation to continue Three timelines are available b commitment to any of these. C PMRS for development and ma supply. Request for compliance
Qualification of new drug substance supplier	Medium	Maintain Drug Substance Supply	Q3/FY04	HM/VP	Tateyama Kasei and FIS to be quazepam drug substance. Dec quazepam from FIS. Samples were not micronized. FIS will micronization and activation of from TK for experimental work

[1] BA-Beth Andry GB- Gul Balwani, ADD-Alex D'Addio, GD-Grace Dang, JG-Jeff Gazzara,WH-Weixuan He, JH-John Higson, ML-Mary Lehr, RM-Rick Majos, EM-Ed Mi Vithal Patel, WR-Will Robinson, BR-Bryan Roecklein, CY-Cindy Yayac

COMMERCIAL PRODUCT TECHNICAL SUPPORT (contin

FELBATOL SUSPENSION

Issue/Program	Priority	Critical Path	Timing	Manager	Status/Commen
Qualify Micron Technologies as approved milling site	High	Maintain Supply of Micronized Drug Substance	Q2	GD/VP	FDA approved Micron Technolo containing three month stabilit second batch was approved or milled felbamate are currently 2C0805 for particle size and 2E foreign material.

SOMA 350

Transfer Manaufacturing Process to Decatur Identify critical process parameters	Critical	Maintain Commercial Supply of Tablets	On-going	WR/HM/ JH	Work with Ray Chen to develop that will be used to identify crit manufacturing process for SOM protocol has been received for
Validate specificity for USP assay	High	Response to FDA Inspection	Q3/FY03	HM	Work initiated in response to F Depen and SOMA both comple been issued by Magellan.

SOMA COMPOUND

Validate specificity for USP assay	High	Response to FDA Inspection	Q3/FY03	HM	Work initiated in response to F quotations from Magellan subm Estimated completion date – M cannot achieve the salicylic aci in the USP. Investigations are

SOMA COMPOUND W/CODEINE

Validate specificity for USP assay	High	Response to FDA Inspection	Q3/FY03	HM	Work initiated in response to F quotations from Magellan subm Estimated completion – Mid Oc achieve the salicylic acid retent USP. Investigations are under

PRODUCT DEVELOPMENT

ASTELIN NASAL SPRAY

Issue/Program	Priority	Critical Path	Timing	Manager	Status/Commen
Astelin Double-Strength – Formulation Development	High	Taste Improvement	On-going	GD/VP	Several formulations at higher and/or higher viscosity have be month stability. Five formulati second level of screening. Xemplar Pharmaceutical identif Magellan for spray testing. CD hold pending evaluation of fina
Astelin Double-Strength – Proprietary pump design	Medium	Brand Protection		ADD	Valois has been contacted conc design of a pump for reformula scheduled for 11/15/02 at requ Valois.

ASTELIN/STEROID COMBINATION PRODUCT

New Nasal Solution Product Azelastine HCl and an Approved Steroid	Low	Extension Product for Lifecycle Maintenance	On Hold	ADD/VP/ GD/JH/JG	Project on hold based on evalu analysis of success potential pr

FLUOROFELBAMATE

Develop Fluorofelbamate for IND	High	Demonstration of Fluorofelbamate Safety Profile	Q2/FY03	HM/WH	Developing pre-clinical progran Go" for Phase I Study Fall/Win
Fluorofelbamate Drug Substance Synthesis	High	Drug Supply for Tox Studies and Development of Commercial Process	Q2/FY03	HM/WH	The preparation fluorofelbamat preclinical toxicity study (ca. 4. and the material has been test MedPointe. The Certificates of batches of the fluorofelbamate issued. Quotation approved fo supply (2 Kg) of drug substanc supply targeted for completion Validation of methyl carbamate release.
cGMP Preparation of Fluorofelbamate	High	Phase I Clinical Study	Q2/FY03	HM/WH	F-diol, the penultimate of fluor been prepared in seven batche analytical division for certificate

					release when they are meeting composite sample is taken and

"MM/dd/yy" }

PRODUCT DEVELOPMENT(continued)

FLUOROFELBAMATE (cont.)

Issue/Program	Priority	Critical Path	Timing	Manager	Status/Commen
Impurities required for Tox Studies	High	Drug Supply for Tox Studies	Q2/FY03	HM/WH	Bis-F-carbonate dimers isolated drug substance and those deri were compared by proton NMR experiments indicated that the Currently, the study is focused 15g of the material to be used
F-Diol Analysis	High			HM/WH	HPLC analytical method of F-di which can successfully separat amount of H-diol in F-diol. Wh it will be used in F-diol analysis cGMP campaign of fluorofelbar
Analytical Methods Polymorph Screen	High		Q4/FY03	HM/WH	Six different organic solvents a combinations have been screen form was identified except an preferred orientation) was obs prepared by fast evaporation o result will be confirmed by repe calculating the XRPD powder p A single crystal of fluorofelbam aqueous solution and crystallog collected. The complete struct be available soon.
Therimmune Pilot PK Studies	High		Q3/FY03	HM/BR/ WH	Sample of fluorofelbamate prov pilot PK studies in rodent to de Protocols for dosing solution de approved. PK plasma methods
Phase 1 Clinical Trial and IND Submission				HM/WH/ ML	A detailed timeline for Phase 1 submission is being developed. Therimmune and IT to establis electronic documentation excha

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