

R&D Pipeline News

The best way to innovate

A premier information source of biopharmaceutical R&D

Issue 10 - September 19, 2005

special annual subscription rate
you can save 400 €
more information at:

20 €

www.lamerie.com

Therapeutic Area Edition

Issue 10 - September 19, 2005

This week Antibody Pipeline

Genentech
IN BUSINESS FOR LIFE



- Numerous line extensions for Rituxan, Avastin, Herceptin and Zenapax. **22**
- Opt-in opportunities for Roche in inflammatory & autoimmune indications of MabThera/Rituxan. **22**
- More than 10 new antibody projects in development. **22**

Featured in this Issue

- New Generics Category introduced. **16**
- New Orphan Drug Recommendations & Designations in Europe. **18**

R&D Pipeline News

Part A

Product Type	Category	No. of news	Page
Pharmaceuticals	Cardiovascular & blood	7	3
	Dermatology	3	4
	Gastrointestinal	4	5
	Infectious & toxicology	8	6
	Metabolism & endocrine	4	7
	Neurology & psychiatry	15	7
	Oncology	24	10
	Ophthalmology	2	13
	Orthopedics, dental & surgery	6	14
	Drug Delivery	8	15
	Generics	10	16

Frequent abbreviations	
OI	Open-label
Rx	Randomized
Db	Double-blind
Pc	Placebo-controlled
Co	Cross-over
Pts	Patients
PK	Pharmacokinetic
PD	Pharmacodynamic
PoC	Proof-of-concept
BLA	Biologics License Agreement
NCE	New chemical entity
GRAS	Generally recognized as safe

Part B

Orphan Drug Recommendations & Designations in Europe	26	18
Antibody Pipeline Chugai / Genentech / Roche	23	22
Technology & BioManufacturing Sites	5	28
R&D Collaborations	8	29
R&D Licensing Agreements	3	30

HDE	Humanitarian device exemption
IDE	Investigational device exemption
NDA	New drug application
MAA	Marketing authorization application
SPA	Special protocol assessment

Product Type: Pharmaceutical			TA: Cardiovascular & blood					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
B 051	TAXUS® Express2™	Tubulin	Paclitaxel-eluting coronary stent	Boston Scientific	Medical device with active ingredient	Coronary artery lesions	Market	Study shows significant reduction of 9-mth re-narrowing vs. bare-metal stents in a population with complex lesions read more
B 054	Xact® carotid stent	-	Carotid artery stent	Abbott	Medical device	Carotid artery disease	Approved CE	Received FDA approval of the minimally invasive carotid artery stent to treat pts at risk of stroke; already launched in EU read more
B 057	Flextome™ Cutting Balloon® dilatation device	-	Balloon device with surgical blades (atherotomes)	Boston Scientific	Medical device	Coronary artery blockages resistant to PTCA	Approved	Received clearance from the FDA to market the device and plans to launch the product immediately which is already approved 01/2005 in EU read more
S 104	Thelin™ Sitaxsentan sodium	Endothelin type A receptor antagonism	Small molecule	Encysive Pharmaceuticals	Small molecule	Pulmonary arterial hypertension	MAA NDA	Announced interim data of ongoing extension trial after 1 yr of treatment in support of submission read more
142	ATryn® Rhu antithrombin	Thrombin	Rhu antithrombin	GTC Bio-therapeutics	Protein	Hereditary antithrombin deficiency	MAA	EMA needs more time for completion of the required site inspection process which delays the overall review process read more
S 321	MC-4232	ACE inhibition + purinergic receptor antagonism	Combination of MC-1 and lisinopril	Medicur	Small molecule	Diabetic hypertension	II	Announced that combination product MC-4232 met primary hypertension and metabolic endpoints read more
S 294	Trans NV-04	Antioxidant	Oral metabolite of isoflavone	Novogen	Small molecule	Patients at risk of cardiovascular events	Ib	Study results show significant improvement in blood pressure and arterial stiffness read more

Product Type: Pharmaceutical			TA: Dermatology					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
N 010	Oligopeptide -10	Antimicrobial and woundhealing properties	HB64 peptide	Levlad & Helix BioMedix	Cosme-ceuticals	Acne	Mar- ket	Levlad acquired from Helix BioMedix rights to use its HB64 peptide in natural and organic cosmetics for use in acne OTC treatment, a US \$ 350 mln market read more
S 046	ISA247	immunosuppressive	Trans-isomer of cyclosporine analogue	Isotechnika	Small molecule	Stable moderate to severe psoriasis	III	Announced that 90 % of pts in the phase III trial wish to extend treatment with study drug read more
448	PRTX-100	?	Protein A (by bacterial fermentation)	Protalex	Protein	Pemphigus	IND	FDA released clinical hold on IND; company may start phase I study in healthy volunteers read more

Product Type: Pharmaceutical			TA: Gastrointestinal					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
458	Remicade® infliximab	TNF-alpha	Rec chimeric IgG1 mab	Centocor (J&J) & Schering- Plough & Tanabe Seiyaku	Antibody	Moderately to severely active ulcerative colitis	sBLA	FDA approved use of Remicade in ulcerative colitis, the 5 th approved indication read more
S 324	Entereg® alvimopan	Peripherally acting mu- opioid receptor antagonism	Small molecule	GSK & Adolor	Small molecule	Opioid-induced constipation & related symptoms	III	Announced initiation of phase III clinical program which consists of three studies globally and n=1700 pts read more
S 300	STA-5326	IL-12/IL-23	Oral small molecule	Synta Pharma- ceuticals	Small molecule	Active Crohn's disease	Iib	Initiated a rx, pc study evaluating once-daily, oral STA-5326 read more
S 286	KOS-2187	Motilin agonism	Erythromycin -based small molecule	Kosan Biosciences	Small molecule	Gastrointestinal motility disorders	Precl	Selected KOS-2187 for develop- ment as it is potent, but lacks known side effects read more

Product Type: Pharmaceutical			TA: Infectious & toxicology					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
B 050	GelSite®	Polymer drug delivery technology		DelSite Bio-technologies	Biomaterial	Flu vaccination	DMF	Submitted Drug Master File for manufacturing and use in nasal and other mucosal applications read more
S 322	Cetraxal otic; ciprofloxacin otic	antibiotic	Small molecule 0.2 % solution	Salvat	Small molecule	External otitis	NDA	FDA accepted Salvat's NDA for review read more
087	TNX-355	CD4	Rec humanized mab	Tanox	Antibody	HIV	II	DSMB interim safety review concluded to continue study read more
451	V3526 Venezuelan equine encephalitis vaccine	Subtype 1A/B + related subtype VEE virus strains	Attenuated live vaccine	Dynport Vaccine Company (DVC) (a CSC company)	Vaccine	Venezuelan equine encephalitis	I	Received Fast Track designation status from the FDA read more And entered phase I evaluation read more
452	Botulinum neurotoxin A and B vaccine	Botulinum neurotoxin A and B	Recombinant bivalent botulinm vaccine	Dynport Vaccine Company (DVC) www.csc.com/dvc	Vaccine	Botulinum intoxication (botulism)	I	Received Fast Track designation status from the FDA read more And entered phase I evaluation read more
453	rF1V; Plague vaccine	F1 capsular protein fused to V virulence protein	Recombinant vaccine (E.coli)	Dynport Vaccine Company (DVC) (a CSC company)	Vaccine	Plague from Yersinia pestis	I	Received Fast Track designation status from the FDA read more and entered phase I evaluation read more
	Pandemic avian flu vaccine	Variable surface proteins + unchanging core proteins	DNA vaccine	Vical	Vaccine	Avian influenza	Res	Received US\$ 2.9 mln grant from US NIAID to develop a DNA vaccine against human pandemic avian flu read more
444	siRNA SCV (SARS coronavirus) SC2 and SC5	SCV (SARS corona virus)	siRNA, intranasally delivered	Intradigm Corp	RNA	SARS respiratory infection	Res	Showed effectiveness to prevent and treat SARS in Rhesus monkeys with siRNA against SARS coronavirus (published in Nature Medicine) read more

Product Type: Pharmaceutical			TA: Metabolism & endocrine					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
S 288	Actos® Pioglitazone HCl	Insulin-sensitizer (PPARγ agonism)	Oral small molecule thiazolidinedione	Takeda Pharmaceuticals & Eli Lilly	Small molecule	Type 2 diabetes	Market	Landmark study showed to reduce heart attacks, strokes and deaths by Actos read more
S 304	MD-0727	Cholesterol absorption inhibition		Microbia	Small molecule	hypercholesterolemia	I	Initiated phase I study in healthy human volunteers to evaluate safety, tolerability, PK and PD
S 317	Bonviva® ibandronic acid		Oral, once monthly small molecule bisphosphonate	Roche & GSK	Small molecule	Postmenopausal osteoporosis	Approved	Swiss authorities approved Bonviva which is already approved, but not yet marketed in the US and received a positive opinion from the CHMP of the EMEA read more
S 318	Oporia; lasofoxifene	Selective estrogen receptor modulator	Small molecule estrogen-like	Pfizer & Ligand Pharmaceuticals	Small molecule	Osteoporosis	NDA	Received non-approvable letter from FDA read more

Product Type: Pharmaceutical			TA: Neurology & psychiatry					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
S 315	Inovelon; rufinamide; CGP 33101	Anti-epileptic by membrane-stabilizing effects	Triazole derivative	Eisai	Small molecule	Adjunctive: Lennox-Gastout syndrome in children; Partial-onset seizures in adults	NDA MAA	Eisai submitted a NDA to the FDA for the anti-epileptic drug licensed in from Novartis in 2004; MAA was submitted to EMEA in March 2005 read more

Product Type: Pharmaceutical			TA: Neurology & psychiatry					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
S 325	Adartrel® ropinirole	Dopamine D2 and D3 receptor agonism	Small molecule	GSK	Small molecule	Moderate to severe idiopathic restless leg syndrome	MAA	CHMP of the EMEA issued positive opinion on the MAA of GSK which is already marketed in the US and Australia and approved for Parkinson's disease read more
263	Myozyme® Alglucosidase alpha	Alglucosidase replacement	Rec hu enzyme	Genzyme	Protein	Late onset Pompe disease	BLA MAA	Initiated clinical trial in pts with late onset of disease to provide additional support for Myozyme's use read more
122	Naglazyme® galsulfase	Arylsulfatase B replacement	Rec hu enzyme	Biomarin Pharmaceutical	Protein	Mucopolysaccharidosis VI (Maroteaux-Lamy syndrome)	MAA	Received positive opinion on the MAA from the CHMP of the EMEA; already received approval from FDA read more
457	NovoLog® (insulin aspart)	Insulin receptor	Rhu rapid-acting insulin analog	Novo Nordisk	Protein	Treatment of diabetes in children	sNDA	FDA approved the drug to be used in children, originally approved for use in adults in 2000 read more
S 312	Alzhemed™; 3APS	Soluble amyloid B protein binding	3-amino-1-propanesulfonic (3APS) oral NCE	Neurochem	Small molecule	Mild-to-moderate Alzheimer's disease	III	Launched its European phase III study with an Investigators meeting; the US phase III study completed enrollment read more
N 009	Diachrome®		Chromium picolinate and biotin containing formula	Nutrition 21	Nutraceutical	Type 2 diabetes with antidiabetic treatment	Clin GRAS*	A rx, db, pc 12-wk study showed an average 0.7-1.9% point reduction in HbA1c levels by Diachrome read more
B 049	Precision™ spinal cord stimulation system		Neurostimulation system medical device	Boston Scientific	Medical device	Chronic pain	CE marked	Received European approval as medical device and plans to start launch of the product in Europe in 2005 read more

Product Type: Pharmaceutical			TA: Neurology & psychiatry					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
S 050	Bicifadine	Serotonin- + norepinephrine reuptake inhibitor	Small molecule	DOV Pharmaceutical	Small molecule	Chronic lower back pain	III	Initiated additional phase III study in chronic lower back pain read more
S 050	Bicifadine	Serotonin- + norepinephrine reuptake inhibitor	Non-narcotic small molecule	DOV Pharmaceuticals	Small molecule	Moderate to severe pain following bunioneectomy surgery	III	Produced significant analgesic effect comparable to tramadol in first of four phase III trials read more
S 308	Keppra® levetiracetam	Unknown (anti-epileptic)	Oral small molecule	UCB	Small molecule	Epilepsy with partial or generalized tonic-clonic seizures	III	Phase III study with monotherapy met its non-inferiority, primary endpoint in comparison with carbamazepine, drug approved for partial onset seizures in adults and children read more
207	Miraxion®; LAX-101	Phospholipase A2 and caspases	Semi-synthetic highly purified eicosapentaenoic acid (EPA)	Amarin	Natural	Huntington's disease Depressive disorder	III II	Reached agreement with the FDA under SPA procedure for the design of two pivotal clinical trials of Miraxion to be conducted in 540 pts in the US and Europe read more
455	Campath®; MabCampath alemtuzumab	CD52	Rec humanized IgG1 mab	Genzyme & Schering	Antibody	Active relapsing-remitting multiple sclerosis	II	Interim results of phase II study comparing alemtuzumab once a year with interferon beta-1 show a large treatment effect in favor of alemtuzumab after 1 yr; prepare phase III study; 3 cases of ITP occurred read more
232	NicVax™ Nicotine conjugate vaccine	Active immunization to nicotined	Nicotine derivative + carrier protein	Nabi Biopharmaceuticals	Vaccine	Nicotine addiction and smoking relapse	II	Received a US\$ 4.1 mln grant to fund development read more
S 289	NRP290	Opioid receptor	Hydrocodone conditionally bioreversible derivative	New River Pharmaceuticals	Small molecule	Pain	I	Presented phase I healthy volunteers PK data after single doses showing bioavailability comparable to hydrocodone read more

Product Type: Pharmaceutical			TA: Oncology					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
S 314	Photofrin PDT	Photodynamic therapy with 630 nm laser light activation (reactive radicals)	Photofrin / Photobarr; porfimer sodium	Axcan Pharma	Medical device	Prevention of esophageal cancer in high risk pts	Market	Photofrin PDT + omeprazole reduced occurrence of esophageal cancer in pts with high grade dysplasia associated with Barrett's esophagus in 5-yr observation period read more
450	Herceptin® trastuzumab	HER2	Rec humanized IgG1 mab	Genentech	Antibody	Women with Her2+ metastatic breast cancer	Market	Interim results of 4 th phase III study with herceptin plus chemotherapy show improved disease-free survival in early stage Her2+ breast cancer read more
S 293	Aromasin® exemestane	Hormonal treatment	Small molecule	Pfizer	Small molecule	Adjuvant treatment of estrogen-positive invasive early breast cancer after 2-3 yrs of tamoxifen	Approved	Received European approval by the MRP procedure for further indication read more
459	Neulasta® pegfilgrastim	G-CSF receptor	Pegylated rec methionyl human G-CSF	Amgen	Protein	Pts receiving myelosuppressive chemotherapy with at least a 17 % risk of febrile neutropenia	Market	FDA accepted update on prescribing information including now data from landmark phase III study showing efficacy also in cancer pts undergoing moderately myelosuppressive chemotherapy read more
S 295	Revlimid® lenalidomide	Immunomodulatory drug	Thalidomide analogue	Celgene	Small molecule	Transfusion-dep. anemia due to low- or intermediate-1-risk myelodysplastic syndrome + deletion 5q cytogenetic abnormality	NDA	read briefing docs FDA advisory Committee recommended Revlimid for approval, studies in other oncology indications (MM, MDS, CLL, solid tumors) are ongoing read more

Product Type: Pharmaceutical			Category: Oncology					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
S 296	Xinlay™ atrasentan	Selective endothelin A receptor antagonism	Oral small molecule	Abbott	Small molecule	Hormone-refractory prostate cancer with bone metastases	NDA	read briefing docs FDA Advisory Committee did not recommend the drug for approval, phase III study with earlier stage HRPC is ongoing read more
S 285	Sorafenib; BAY43-9006	Multi-kinase: RAF, VEGF-R2, VEGF-R3, KIT, FLT-3, RET	Oral small molecule inhibitor	Bayer & Onyx	Small molecule	Advanced renal cell carcinoma	MAA; NDA	Bayer submitted to the EMEA a MAA for sorafenib in kidney cancer read more FDA accepted submission and granted priority review read more
S 309	Arranon® nelarabine injection	DNA synthesis inhibition (cytotoxic)	Small molecule chemotherapeutic, a prodrug of ara-G (arabinosid)	GSK	Small molecule	Refractory T-cell acute lymphoblastic leukemia and lymphoblastic lymphoma	NDA	FDA Oncology Advisory Committee recommended accelerated approval of Arranon pediatric pts read more
S 61	Tarceva; erlotinib	EGF-R1 tyrosine kinase	Oral small molecule	OSI Pharmaceuticals	Small molecule	Treatment naive advanced pancreatic cancer + gemcitabine	sNDA	briefing docs were published; FDA staff question new use of Tarceva read more ; FDA Oncology Drug Advisory Committee recommended approval of pancreatic cancer label read more
S 116	Taxotere® docetaxel	Tubulin	Semisynthetic small molecule	Sanofi-Aventis	Small molecule	Various cancers Early stage Her2+ breast cancer	Market III	Interim results of phase III study of taxotere-including chemotherapy plus trastuzumab show significantly improved disease free survival read more
65	Provenge; APC8015	Prostatic acid phosphatase (rec PAP used to stimulate)	Activated autologous dendritic cell therapy	Dendreon	Cells	Advanced prostate cancer Early stage PC	Pre-BLA III	Decided to submit BLA after meeting with FDA which concluded that clinical data were sufficient for BLA submission read more

Product Type: Pharmaceutical			Category: Oncology					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
S 252	Acapodene® toremifene citrate	Selective estrogen receptor modulation	Small molecule	GTx	Small molecule	High grade prostatic intraepithelial neoplasia (PIN)	III	Received FDA response under SPA protocol on design of phase III trials read more
079	L-BLP25	MUC-1	Liposomal synthetic peptide vaccine	Biomira & Merck KGaA	Vaccine	Advanced non-small cell lung cancer	I Ib	Engaged clinical CRO for conduct of planned phase III study scheduled to commence by end of 2005 read more
079	L-BLP25	MUC-1	Liposomal synthetic peptide vaccine	Biomira & Merck KGaA	Vaccine	Advanced non-small cell lung cancer	I Ib	Completed enrollment of a 20-pts phase II safety study to assess the formulation to be used in phase III read more
446	INGN 225; Ad-p53	P53 tumor suppression	Autologous dendritic cells + adenovector p53 gene	Introgen Therapeutics	Vaccine	Advanced small cell lung cancer	II	Interim results from ongoing phase II study show good tolerability and appears to sensitize for chemotherapy read more
S 259	Xcytrin®; Motexafin gadolinium; PCI-0120	Thioredoxin reductase inhibition	Small molecule + paramagnetic gadolinium	Pharmacyclics	Small molecule	Brain metastases from solid tumors + radio-surgery	II	Started patient enrollment of phase II study with planned n=45 pts in North America read more
339	HuMax-CD20	CD20	Rec fully human mab	Genmab	Antibody	Relapsed CLL	I/II	Announced positive interim results after 11 wk, the MTD not yet reached read more
S 291	PXD101	Histone deacetylase (HDAC)	Small molecule	CuraGen & Topotarget	Small molecule	Advanced solid tumors incl. ovarian cancer	Ib	Initiated phase Ib clinical trials in combination with carboplatin and/or paclitaxel read more
S 313	Sodium stibogluconate; VQD001	Target newly discovered: specific protein tyrosine phosphatase	Small molecule used for leishmaniasis treatment	Cleveland Clinic Taussig Cancer Center & VioQuest Pharmaceuticals	Small molecule	Solid, lymph node or bone marrow tumors	I	Initiated enrolling patients in the phase I study to evaluate MTD in combination with IFN-2b read more

Product Type: Pharmaceutical			Category: Oncology					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
S 297	TPI 287	Tubulin	Taxane derivative	Tapestry Pharmaceuticals	Small molecule	Cancer	I	Will give update on compound in a webcast read more
429	GTO-2040	R2 component of ribonucleotide reductase	antisense	Lorus Therapeutics & NCI	RNA	Various cancers	Clin	Ongoing Steering Committee assessment on six active clinical studies
445	ICS-283	VEGF	siRNA	Intradigm	RNA	Colorectal cancer	Precl	Expect to enter the clinic in mid 2005 read more
S 303	ENMD-1198	HIF-1alpha inhibition	2 nd generation analog of 2-methoxyestradiol	EntreMed	Small molecule	Cancer	Precl	Is conducting IND enabling studies to submit IND by end of 2005 read more
449	INGN 007	ADP gene overexpression	Oncolytic virus	Introgen	DNA	Cancer	Precl	Animal studies show the safety of the improved oncolytic virus read more

Product Type: Pharmaceutical			Category: Ophthalmology					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
456	Macugen® Pegaptanib sodium	VEGF	Pegylated oligonucleotide (aptamer)	Eyetech Pharmaceutical & Pfizer	RNA	Neovascular (wet) age-related macular degeneration	Market MAA	The CHMP of the EMEA issued a positive opinion on Macugen which is already approved in the US read more
447	ZFP TV™	VEGF- turn off; PEDF: turn on	Plasmid DNA encoding DNA-binding protein transcription factors	Sangamo Biosciences	DNA	Age-related "wet" macular degeneration	Res	Reported animal study results showing effectiveness of combined therapy read more

Product Type: Pharmaceutical			TA: Orthopedics, dental & surgery					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
B 053	TruTunnel™ BGS Plug		PolyGraft® polymeric scaffold (polylactide-co-glycolide copolymer + calcium sulfate)	OsteoBiologics	Medical device	Ligament reconstruction procedures	Market	Announced launch of its bone graft substitute material for ligament reconstruction procedures read more
B 055	DuraSeal® Sealant		Synthetic absorbable hydrogel with dual syringe applicator	Confluent Surgical	Medical device	Elective pulmonary resection	CE mark	Received CE mark for its Sealant in pulmonary surgery, already approved in neurosurgery read more
B 056	BioBlanket™ soft tissue repair patch		Resorbable collagen sheet	Kensey Nash	Medical device	Repair of hernias; rotator cuff repair surgery	Approved	FDA approved indications for its surgical mesh, first approval in 2004 read more
B 048	Xpanse™ bone insert device		Demineralized bone fiber + cancellous bone chips	Osteotech	Medical device	Orthopedic and reconstructive bone graft procedures	Approved	Osteoinductive, -conductive and -conforming device tissue graft to be introduced read more
B 048	GraftCage™ TLX vertebral body replacement device		Polymer device	Osteotech	Medical device	Transverse spinal interbody procedures	510 (k) pending	To be introduced at forthcoming meeting read more
B 052	Periowave® photo-dynamic disinfection system	Laser handpiece	Photo-sensitive compound	Ondine Biopharma	Medical device	Chronic periodontitis	Clin	Pilot clinical study showed that photodynamic disinfection in addition to scaling and root planing was superior to scaling and root planing alone read more

Product Type: Pharmaceutical			Category: Drug Delivery					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Delivery System	Company	Indication	R&D Stage	Message
S 298	Alvesco® Ciclesonide inhaled	Anti-inflammatory	Inhaled corticosteroid	Inhaler system	Sanofi-Aventis & Altana & Tejin	Moderate to severe persistent asthma	Appr letter Market	Long term use of inhaled ciclesonide does not affect the HPA-axis of the neuroendocrine system read more
S 290	Actiq® sugar free	Opioid receptor	Fentanyl small molecule – sugar-free formulation	Oral transmucosal lozenge with handle	Cephalon	Breakthrough cancer pain	Approved	FDA approved the sugar-free formulation of Actiq for the same indication read more
S 292	SPD476	Anti-inflammatory	Mesalamine (salicylic acid derivative)	Multi-Matrix System™ high strength	Shire Pharmaceuticals	Mildly to moderately active ulcerative colitis	III	Once-a-day high-dose formulation of mesalamine was active in inducing remission read more
S 301	Amoxicillin PULSYS	Antibiotic	Once-daily amoxicillin antibiotic	Pulsatile delivery technology PULSYS	Advancis Pharma	Pharyngitis & tonsillitis in adults and adolescents	III	Decided to conduct another phase III trial with 10-d treatment (instead of 7 d) of its frontloaded regimen read more
136	Oral-lyn™ oralin	Insulin receptor	Rec insulin	Buccal drug delivery with RapidMist spray	Generex Biotechnology	Type 1 and 2 diabetes	II	Study found similar glucodynamic responses between Oral-lyn and sc Humulin read more Approved in Ecuador
S 302	Sterile lidocaine patch	Analgesic	Lidocaine	Patch with sustained-release	Adolor Corp	Post-surgical incisional pain	II	Initiated a phase II study in hernia repair surgery with its sterile lidocaine patch read more
S 156	Davanat® / 5-FU	Lectin (protein receptor for Carbosome)	Poly-saccharide	Carbosome™	Pro-Pharmaceuticals	Cholangiocarcinoma 1 st line treatment	I	Submitted a clinical protocol of a phase II study protocol in cholangiocarcinoma; a phase II colorectal cancer study is ongoing read more
S 287	TerbiFoam™ 2 % foam	Antifungal	Terbinafine antifungal	Emollient Foam base	Foamix	Tinea pedis (athlete's foot)	I	Announced plan to initiate phase II clinical study after study approval by EC read more

Product Type: Pharmaceutical			Category: Generic					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
S 299	Leflunomide Tbls.	Dihydro-orotate dehydrogenase inhibition	Generic equivalent to Sanofi-Aventis' Arava®	Barr Therapeutics	Rheumatoid & immune	Active rheumatoid arthritis in adults	ANDA approved	Received approval from FDA and plan to launch immediately; US sales of leflunomide products total US\$ 238 mln read more
S 311	Leflunomide Tbls. (Par)	Dihydro-orotate dehydrogenase inhibition	Generic equivalent to Sanofi-Aventis' Arava®	Par Pharmaceuticals & Kali Laboratories	Rheumatoid & immune	Active rheumatoid arthritis	ANDA approved	Received final approval from FDA; US sales of Arava exceed US\$ 200 mln (IMS) read more
S 305	Gabapentin (Ranbaxy)		Generic equivalent to Pfizer's Neurontin®	Ranbaxy Pharmaceuticals	Neurology & psychiatry	Postherpetic neuralgia & partial seizures	ANDA approved	Received final approval from FDA to market gabapentin read more
S 306	Tolterodine tartrate (Ranbaxy)	Competitive muscarinic receptor antagonism	Generic equivalent to Pfizer's Detrol	Ranbaxy Pharmaceuticals	Genito-urinary	Overactive bladder	ANDA	Received tentative approval from FDA read more
S 307	Metronidazole Topical Gel USP 0.75% (Fougera)	Antifungal	Generic equivalent to Galderma's MetroGel®	Fougera	Infectious	Rosacea	ANDA	Received tentative approval from the FDA read more
S 310	Metformin hydrochloride ER Tbls. (Mylan)	Improves glucose tolerance	Generic equivalent to BMS's Glucophage®	Mylan	Metabolism & endocrine	Type 2 diabetes	ANDA	Received final approval from the FDA; Glucophage sales: US\$ 173 mln (IMS) read more
S 320	Metformin hydrochloride XR Tbls. (Impax)	Improves glucose tolerance	Generic equivalent to BMS's Glucophage®	Impax Laboratories	Metabolism & endocrine	Type 2 diabetes	ANDA	Received final approval from the FDA; Glucophage XR US sales: US\$ 23 mln (IMS) read more

Product Type: Pharmaceutical			Category: Generic					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Product Category	Indication	R&D Stage	Message
S 316	Fexofenadine hydrochloride (Prasco)	Histamine H1-receptor antagonism	Generic equivalent to Sanofi-Aventis Allegra®	Prasco Laboratories & Sanofi-Aventis	Pulmonary & respiratory	Seasonal allergic rhinitis	ANDA	Sanof-Aventis signed a distribution and supply agreement with Prasco for its Allegra as authorized generic fexofenadine read more
S 319	Famotidine Tbls. (Perrigo)	Histamine H2-receptor antagonism	Generic equivalent of Merck's Pepcid®	The Perrigo Company	Gastro-intestinal	Active duodenal ulcer, benign gastric ulcer and gastroesophageal reflux disease	ANDA	Received tentative approval from FDA; final approval upon patent expiration on Sept. 23, 2006 read more
S 323	Ribavirin tbls.	Unclear (nucleoside analog)	Generic equivalent of Roche's Copegus®	Teva Pharmaceuticals	Infectious	Hepatitis C virus infection in combination with peg-IFN alfa-2a	ANDA	FDA granted tentative approval; copegus has annual sales of approx. US\$ 206 mln read more

Product Type: Positive recommendations for Orphan Drug Designations by the COMP* of the EMEA in September 2005

ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company / Representative	Product Category	Indication	R&D Stage	Message
	Rec modified vaccinia virus Ankara expressing TB antigen 85A	Tuberculosis antigen 85A	Rec viral vector with TBC antigen 85A plasmid (DNA vaccine)	University of Oxford, UK	Vaccine	Prevention of tuberculosis in BCG vaccinated individuals		Based on "insufficient return on investment" criterion
				Orphix Consulting GmbH	Small molecule	Primary malignant bone tumors		Based on "prevalence" criterion
				The Mathews Consultancy Ltd.	Small molecule	Peripheral T-cell lymphoma		
	alfimeprase			Quadramed		Acute peripheral arterial occlusion		
	Bacterial lipase			Nordmark Arzneimittel GmbH u. Co. KG		Malabsorption due to exocrine pancreatic enzyme insufficiency		
	Levamisol hydrochloride			ACE Pharmaceuticals BV		Nephrotic syndrome		
	Mannitolum			Stricent AB		Cystic fibrosis		
	Oligonucleotide phosphorothioate			Oligovax		Glioma		

* COMP: Committee for Orphan Medicinal Products

Product Type: Positive recommendations for Orphan Drug Designations by the COMP of the EMEA in September 2005

ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company / Representative	Product Category	Indication	R&D Stage	Message
	Peptide 144	TGF-beta-1 inhibitor	Peptide	Digna Biotech S.L.	Peptide	Systemic sclerosis		
	Peptide 144	TGF-beta-1 inhibitor	Peptide	Digna Biotech S.L.	Peptide	Localised scleroderma		
	rec microbial lipase		Rec protein	Solvay Pharmaceuticals	Protein	Malabsorption due to exocrine pancreatic enzyme insufficiency		
	Human <i>Staphylococcus aureus</i> Immunoglobulin	Passive immunization	Human plasma derived Ig	Nabi Biopharmaceuticals Europe Ltd.	Antibody	Staphylococcus aureus bacteremia		
	Tilarginine acetate	Nitric oxide inhibition	Synthetic small molecule	Dr. Ulrich Granzer	Small molecule	Cardiogenic shock	II	Presumably for Arginox Pharmaceuticals, prepares for phase III
	Imatinib mesilate (Gleevec)	Bcr-abl tyrosine kinase, PDGF-R, SCF-R and kit tk	Small molecule	Novartis Europharm Ltd.	Small molecule	Chronic eosinophilic leukemia + hypereosinophilic syndrome	Market	Written procedure on August 19, 2005

* COMP: Committee for Orphan Medicinal Products

Source of information: <http://www.emea.eu.int/pdfs/human/comp/29923305en.pdf>

Product Type: Positive decisions of the European Commission for Orphan Drug Designations in July/August 2005

ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company / Representative	Product Category	Indication	R&D Stage	Message
	Hydrocortisone (modified release tbl.)			Prof. Richard JM Ross	Small molecule	Congenital adrenal hyperplasia		
	Nemorubicin hydrochloride			Nerviano Medical Sciences Srl	Small molecule	Hepatocellular carcinoma		
	4-imino-1,3-diazobicyclo-[3.1.0]-hexan-2-one			ICON Clinical Research Ltd.	Small molecule	Pancreatic cancer		
	AAV vector + mod. U7-snRNA gene		Adeno-associated viral vector with modified gene for u7-snRNA	Généthon	DNA	Duchenne muscular dystrophy		
	Mifepristone	Anti-progestational: progesterone receptor	Synthetic steroid	Laboratoire HRA Pharma	Small molecule	Cushing's syndrome secondary to ectopic ACTH secretion		
	Anti-CD3 (SPV-T3a)-ricin A chain + anti-CD7 (WT1)-ricin A chain fusion proteins	CD3 and CD7	Immuno-toxin combination product	Henogen S.A.	Antibody	Graft-versus-host disease		

Product Type: Positive decisions of the European Commission for Orphan Drug Designations in July/August 2005

ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company / Representative	Product Category	Indication	R&D Stage	Message
	A methyl-sulfonyl-acetamide			Nippon Shinyaku Co. Ltd.	Small molecule	Pulmonary arterial hypertension + chronic thromboembolic pulmonary hypertension		
308	Kepra; levetiracetam	Unknown (anti-epileptic)	Small molecule	UCB S.A.	Small molecule	Progressive myoclonic epilepsies	III	
	TMC207 (R207910)	Anti-mycobacterial	Quinoline-ethanol	Tibotec Pharmaceuticals	Small molecule	Tuberculosis		
	ADA gene therapy	Adenosine deaminase (ADA)	Autologous CD34+ cells with retroviral vector for ADA gene	Fondazione Telethon	Cells	SCID due to ADA		
	Extract of Sorghum bicolour leaf, Pterocarpus osun stem, Piper guineense seed and Caryophylli flower		Extract of botanical products	Xechem UK Ltd.	Natural	Sickle cell disease		
	Adult stem cells	Tissue regeneration	Human autologous mesenchymal stem cells extracted from adipose tissue	Cellerix S.L.	Cells	Anal fistula	Clin	

Featured Company Product Pipeline: Antibody Pipeline Genentech / Chugai / Roche

Product Type: Pharmaceutical			Category: Line extensions					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Therapeutic Area	Indication	R&D Stage	Message
344	Mabthera® / Rituxan® rituximab; R105	CD20	Rec chimeric IgG1 mab	Biogen Idec, Genentech, Roche	Inflam-matory	Moderate to severe rheumatoid arthritis (RA);	II	Projected filing date in 2007
						RA pts not responding to anti-TNF therapy	III	Projected filing date in 2005
344	Mabthera® / Rituxan® rituximab; R105	CD20	Rec chimeric IgG1 mab	Biogen Idec, Genentech, Roche	Oncology	1 st line CLL	III	Projected filing date post 2008
						relapsed CLL	III	Projected filing date in 2005
						maintenance indolent NHL	III	
460	Avastin™ bevacizumab R435	VEGF	Rec humanized IgG1 mab	Genentech & Roche	Oncology	Metastatic breast cancer;	III	Projected filing in 2006
						NSCLC	III	Projected filing in 2006
						Pancreatic cancer	III	Projected filing in 2008
						Renal cell cancer	III	Projected filing in 2008
						1 st line therapy ovarian cancer	III	Projected filing post 2008
						prostate cancer	III	

Sources of information: [Presentation by CEO of Roche Pharma](#)

[Roche Pharma Pipeline as of June 30, 2005](#)

[Genentech Pipeline as of July, 2005](#)

Product Type: Pharmaceutical			Category: Line extensions					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Therapeutic Area	Indication	R&D Stage	Message
450	Herceptin® trastuzumab R597	HER2	Rec humanized mab	Genentech & Roche	Oncology	Adjuvant for breast cancer;	III	Projected filing in 2006
						combination with taxotere for metastatic breast cancer;	III	Projected filing in 2006
						advanced gastric cancer	III	Projected filing in 2008
277	Zenapax® Daclizumab R35	CD25	Rec humanized mab	PDL & Roche	Pulmonary & respiratory	Asthma	II	

Sources of information: [Presentation by CEO of Roche Pharma](#)
[Roche Pharma Pipeline as of June 30, 2005](#)
[Genentech Pipeline as of July, 2005](#)

Product Type: Pharmaceutical			Category: Opt-in opportunities for Roche						
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Therapeutic Area	Indication	R&D Stage	Message	
463	Anti-NGF	NGF	Rec humanized mab	Genentech & Rinat Neuroscience	Neurology	Acute and chronic pain	I		
344	Mabthera® / Rituxan® / rituximab; R105	CD20	Rec chimeric IgG1 mab	Biogen Idec, Genentech, Roche	Inflammatory	Primary progressive multiple sclerosis	III		
						RR MS	II		
						Vasculitis	III		
						Systemic lupus erythematoses	III		
						Lupus nephritis	III		

Sources of information: [Presentation by CEO of Roche Pharma](#)
[Roche Pharma Pipeline as of June 30, 2005](#)
[Genentech Pipeline as of July, 2005](#)

Product Type: Pharmaceutical			Category: Participation through Genentech						
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Therapeutic Area	Indication	R&D Stage	Message	
208	Lucentis® Ranibizumab	VEGF	Rec humanized Fab fragment	Genentech & Novartis	Ophthalmology	Age-related (wet) macular degeneration	III		
268	Xolair™ omalizumab	IgE	Rec humanized mab	Genentech & Novartis / Tanox	Pulmonary & respiratory	Pediatric asthma Peanut allergy	III II		
461	BR3-Fc	BAFF (BlyS) ligand on B-cells	Fusion protein of sol BR3 + Ig	Genentech	Rheumatoid	Rheumatoid arthritis	I		

Product Type: Pharmaceutical			Category: Participation through Chugai						
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Therapeutic Area	Indication	R&D Stage	Message	
462	CAL	PTH-related protein	Rec humanized mab	Chugai (with license from Abgenix)	Oncology	Bone metastases Hypercalcaemia of malignancy	I/II I		

Sources of information: [Presentation by CEO of Roche Pharma](#)

[Roche Pharma Pipeline as of June 30, 2005](#)

[Chugai Development Pipeline as of August 4, 2005](#)

[Genentech Pipeline as of July, 2005](#)

Featured Company Product Pipeline: Antibody Pipeline Genentech / Chugai / Roche

Product Type: Pharmaceutical			Category: New entities					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Therapeutic Area	Indication	R&D Stage	Message
021	Actemra® tocilizumab MRA R1569	Interleukin-6	Rec humanized mab	Chugai & Roche	Immune	Castleman's disease Crohn's disease SLE	Market II I	Launched in June 2005 in Japan In Japan In USA
021	Actemra® tocilizumab MRA R1569	Interleukin-6	Rec humanized mab	Chugai & Roche	Inflammatory	Rheumatoid arthritis; Sytemic onset juvenile idiopathic arthritis	III III	Projected filing date in 2007 Japan phase III; in UK phase II
021	Actemra® tocilizumab MRA R1569	Interleukin-6	Rec humanized mab	Chugai & Roche	Oncology	Multiple myeloma	II I	In France phase II, in US phase I
464	Omnitarg™; Pertuzumab R1273	HER2 dimerization inhibition	Rec humanized IgG1 mab	Genentech & Roche	Oncology	Ovarian cancer; metastatic breast cancer	II II	Projected filing date post 2008, In combination with chemotherapy
465	R1550; huHMFG1; (ex Therox)	MUC1	Rec humanized mab	Antisoma & Roche	Oncology	Metastatic breast cancer	I	read more
466	2nd gen. anti-CD20; R1594	CD20	Rec humanized mab	Biogen Idec; Genentech & Roche	Inflammatory	Rheumatoid arthritis	II	Projected filing date in 2008
466	2nd gen. anti-CD20; R1594	CD20	Rec humanized mab	Biogen Idec; Genentech & Roche	Oncology	Hematologic malignancies	I	

Sources of information:

[Roche Pharma Pipeline as of June 30, 2005](#)
[Genentech Pipeline as of July, 2005](#)

[Chugai Development Pipeline as of August 4, 2005](#)

Product Type: Pharmaceutical			Category: New entities					
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Company	Therapeutic Area	Indication	R&D Stage	Message
	R1507	Growth factor receptor	Rec fully human mab	Roche	Oncology	Solid tumors	0*	Antibody from Genmab alliance, active in various animal tumor models, currently in GLP tox studies read more
	R1599	Interleukin-1 receptor	Rec mab		Inflam-matory			
		T-cell activation blockade	Rec fully human mabs +/- effector function	Roche & Genentech	Immune	Inflammatory diseases and transplantation	0*	Mabs with and without effector function will compared with use for inflammation such as rheumatoid arthritis and asthma read more
	R1450	New mechanism leading to plaque formation	Rec mab	Roche	Neurology	Alzheimer's disease	0*	Mab with new mechanism of action has potential to inhibit progression of disease
			Rec mab	Roche	Cardio-vascular		0	

*, phase 0 = phase with studies enabling entry into humans (non-clinical development)

Sources of information: [Presentation by Head of Pharma Research Penzberg](#)

Product Type: Technology					
ID No.	Company	Product or Technology	Product Category	Application Field	Message
T 025	Intradigm	TargeTran™: Advanced synthetic nanoparticle system	Drug delivery	Delivery of siRNA to target tissue	Technology targets RNAi therapeutics to specific disease tissues with systemic administration (self-assembling layered nanoparticle) read more
T 026	SuperArray Bioscience	RT2Profiler™ PCR Array	PCR-based expression profiling	Pathway focused DNA microarray	Announced the release of a PCR based technique for profiling the expression of a focused panel of genes read more
T 027	Sigma	Panorama™ Ab Microarray	Antibody array	To identify gene regulation in cell or tissue extracts	Sigma launched the new antibody array for identifying gene regulation in cell or tissue extracts compatible with human, rat and mouse proteins read more
T 028	Open Biosystems	Expression Arrest™ shRNA (mir) mouse library	Gene silencing	Validation of gene function, probing interaction of genes	The Micro-RNA-adapted RNAi library covers the entire mouse genome read more

Product Type: BioManufacturing Sites								
ID No.	Product Name	Target / Mechanism of Action	Class of Compound	Originator Company	Manufacturing Company	Fermentation Cell Line	R&D Stage	Message
M 025	Biologics-based anti-biowarfare therapies		Biologics	-	Morphotek	Mophogenics cell line technology	Res	Morphotek received a US\$ 6.3 mln grant from the DARPA to develop cell lines suitable for scalable manufacturing of biologic-based anti-biowarfare therapies read more

Product Type: R&D Collaborations

ID No.	Subject of Collaboration	Partner 1	Technology 1	Partner 2	Technology 2	Message
C 062	Biomarker research agreement	Ipsogen SAS Genaissance	Collection of clinical trial samples; Genotyping & data analysis	Two global pharmaceutical companies		The two biotech companies collaborate with Big Pharma to identify biomarkers from tumor biopsies to show effects of anti-cancer drugs read more
C 063	Denge fever vaccine delivery	Walter Reed Army Institute of Research	Vaccine delivery system using small needles	Cyto Pulse Sciences		The parties collaborate to develop a DNA vaccine delivery system against Dengue fever read more
C 064	Drug discovery	Avalon Pharmaceuticals	AvalonRx® large scale gene expression analysis	Novartis	Target, chemical library, lead optimization	The parties collaborate to discover small molecule therapeutics targeted against an undisclosed Novartis' pathway; Avalon uses its chemical genomics technology read more
C 065	Avian flu vaccine production process	Novavax	H9N2 avian flu small scale production process	Wave Biotech	Process and equipment expertise	The parties collaborate to develop a commercial scale production process on pandemic influenza vaccines starting with the H9N2 process read more
C 066	Therapeutic cell lines for diabetes	Sangamo Biosciences	ZFP transcription factor technology	LifeScan (J&J)	Research funding	The parties extended the collaboration for the second time; ZFP TFs to specifically regulate the expression of genes critical for the cell therapeutics read more
C 067	Medicinal chemistry research	ChemDiv	Small molecule chemistry CRO services	Schering	Funding	ChemDiv will apply its expertise to support ongoing medicinal chemistry programs at Schering read more
C 068	Biomarkers in atherosclerosis	FoxHollow	Collection of atherosclerotic plaques (SilverHawk™ plaque excision system)	Merck & Co.	Pharmacogenomic analysis & compound profiling	The collaboration will focus on analyzing atherosclerotic plaque from patient arteries to identify biomarkers and use them for profiling compounds read more
C 069	Role of HIF-1alpha inhibition in treatment of cancer	EntreMed	2-methoxy-estradiol (2ME2) + ENMD-1198	NCI	Cell lines, animal models,	The collaboration aims at elucidating the mechanism of action of EntreMed's lead anti-HIF-1alpha compounds read more

Product Type: R&D Licensing Agreements

ID No.	Subject of License	Licensor	Licensee	Territory	Rights	Message
L 054	UltiMAB® Human Antibody Development System	Medarex	ImClone Systems	?	Use of UltiMAB for oncology mabs	Medarex granted licensing rights for its antibody technology to ImClone in exchange for license fees, milestone payments and royalties on future sales read more
L 055	Non-viral gene delivery technology	Vical	Merck & Co.		Option for rights to use technology	Vical granted to Merck renewable options for rights to use its technology in exchange for non-exclusive rights from Merck to use technology for vaccines against HIV read more
L 056	Phase I nail fungus product	NexMed	Novartis	global	Exclusive rights for NM100060 nail lacquer treatment	NexMed exclusively licensed its phase I product to Novartis; the product is available as a nail lacquer for treatment of onychomycosis read more