

# EXHIBIT

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# Overview of R&D Activities

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Vice President  
General Manager of Strategic Planning Dept.  
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August 5, 2005





## **Forward Looking Statements**

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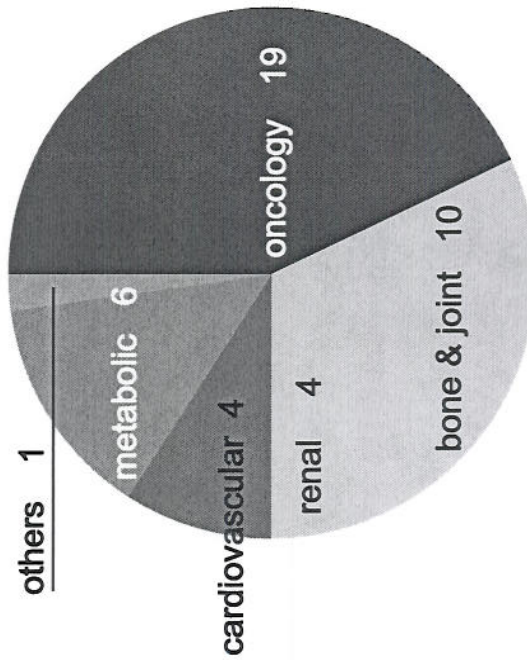
This presentation may include forward looking statements pertaining to the business and prospects of Chugai Pharmaceutical Co., Ltd. (the “Company”). These statements reflect the Company’s current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company’s businesses.



# Current R&D Portfolio

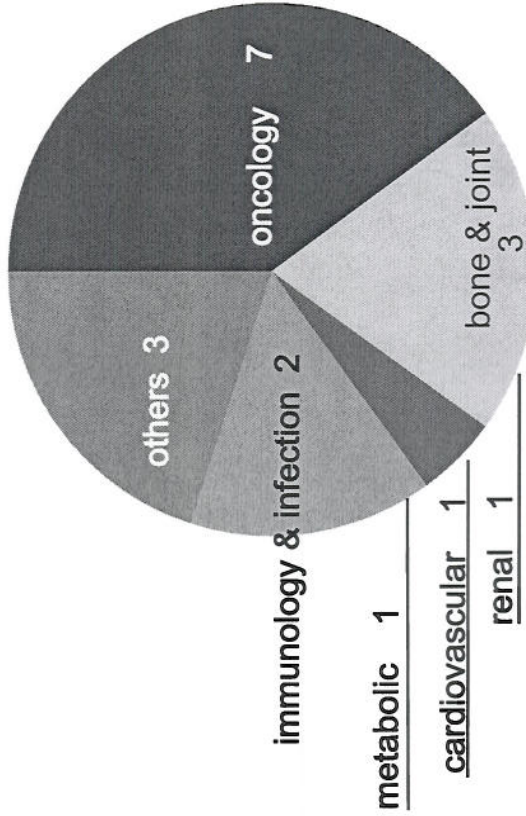
Increased productivity and diversity in our research portfolio

Research Portfolio



44 Projects

Development Portfolio

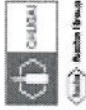


18 NMEs

Including projects currently being prepared for the clinical phase

As of June 2005





# Projects under Development (as of July 2005)

	Phase I	Phase II	Phase III	Filed
<b>Oncology</b>	<i>R435 (Avastin)</i> <i>R1273(Omnitarg)</i> CHC12103 CAL (HM)	<u>MRA (MM)</u> <u>CAL (BM)</u> <i>Xeloda (mCRC)</i> <i>R1415 (Tarceva NSCLC)</i> <i>R744 (CERA)</i>	<i>Herceptin (Adj. BC)</i> Epogin	CGS20267
<b>Bone &amp; Joint</b>		<i>R484 (Bonviva oral)</i> <i>R484 (Bonviva iv)</i> CHS13340	<u>MRA (RA)</u> <u>MRA (so/IA)</u> ED-71	
<b>Renal</b>		<i>R744 (CERA)</i>		
<b>Transplant, Immunology Infection</b>	<u>MRA (SLE)</u> <u>MRA (CA)</u>	MRA (CD)		MRA (CA):Launched <i>R964(Copegus)</i>
<b>Others</b>	<i>R483</i>	<u>GM-611</u> VAL (inj.) VAL (oral)		AVS Sigmart (heart failure) Epogin (autologous transfusion) (premature infants)

(*Italics*: Roche projects, Underlined: Projects for global development)



## Chugai's Oncology Portfolio

Product	Category	Indication	Phase
CGS20267 (Femara®)	Aromatase inhibitor	Breast cancer	Filed
EPOGIN®	Epoetin beta	Chemotherapy-induced anemia	Preparing for filing
HERCEPTIN®	Anti-HER2 Mab	Breast cancer (adjuvant)	P3
XELODA®	Oral FU	Colorectal cancer	P2 completed
		Gastric cancer	P2
R1415 (Tarceva®)	Tyrosine kinase inhibitor	NSCLC	P2
MRA	Anti-IL-6 receptor Mab	Multiple myeloma	P2(France)
R744(CERA)	Continuous Erythropoiesis Receptor Activator	Chemotherapy-induced anemia	P2
CHC12103	Polyglutamate-TXL	Solid tumors	P1 completed
CAL	Anti-PTHrP Mab	Bone metastasis	P1/2(US)
		Hypercalcemia of malignancy	P1 completed
R435 (Avastin®)	Anti-VEGF Mab	Colorectal cancer	P1/2
R1273 (Omnitarg™)	Anti-HER Dimerization Mab	Solid tumors	P1



## January-July 2005 R&D Topics – (1)

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- Jan MRA: started overseas phase III study for rheumatoid arthritis under co-development with Roche
- Mar Closed Tsukuba Research Laboratories
- Mar FS-69: discontinued clinical development
- Apr Relocated Chugai Pharma USA to New Jersey
- Apr MRA: approved for Castleman's Disease in Japan
- Apr Established Forerunner Pharma Research Co., Ltd.
- Apr VAL(oral): started phase II study for decompensated cirrhosis
- Apr R212: discontinued clinical development





## January-July 2005 R&D Topics – (2)

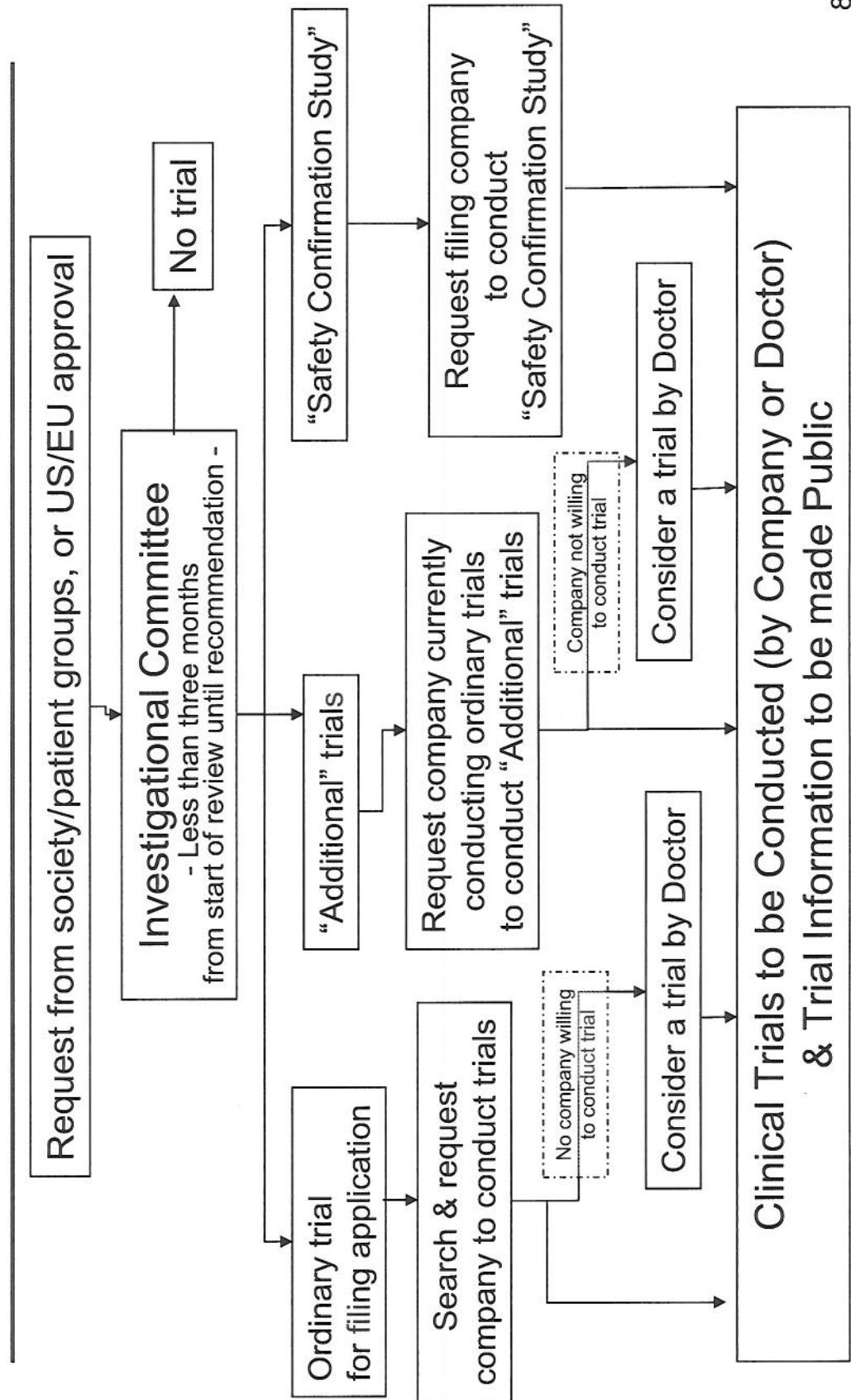
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- June EPOCH: completed phase III study for chemotherapy-induced anemia
- June MRA: completed phase III study for rheumatoid arthritis in Japan
- June R744: started phase II study for chemotherapy-induced anemia
- June R964: filed for chronic hepatitis C in combination with Pegasys®
- June MRA: launched for Castleman's disease
- June R484(oral): started phase II for osteoporosis
- July PB-94: launched in Taiwan
- July GM-611: started preparation for phase III
- July R435: requested by the MHLW "Investigational Committee for Usage of Unapproved Drugs" to conduct Safety Confirmation Study





# Clinical Trials Flow Chart for "Unapproved Drugs"





## Conclusions from the Fifth Investigational Committee for Usage of Unapproved Drugs (held on July 22)

<p>Generic Name Description Indication</p>	<p>&gt; Approval status</p> <ul style="list-style-type: none"> <li>• Conclusions from review (excerpt)</li> </ul>
<p><b>Bevacizumab</b> Antitumor drug (injection) Colorectal cancer</p>	<p>&gt; US/EU (metastatic colorectal cancer)</p> <ul style="list-style-type: none"> <li>• As the clinical usefulness is assumed to be proven from overseas data, early application should be made upon completion of the phase I study conducted in Japan, based on the available overseas &amp; domestic clinical data.</li> <li>• Safety Confirmation Study under FOLFOX4+BV regimen should be conducted while Chugai prepares for filing and while the review process takes place after filing until approval, to collect clinical data consistent with the expected usage after launch in Japan.</li> </ul>
<p><b>Erlotinib</b> Antitumor drug (Oral) Non-small cell lung cancer</p>	<p>&gt; US (locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen)</p> <ul style="list-style-type: none"> <li>• Attention needed to safety such as acute lung injury and interstitial lung disease, as incidences of interstitial pneumonia were observed in phase I clinical trial.</li> <li>• As phase II clinical trial is ongoing in Japan with NSCLC patients previously treated with chemotherapy, the usage of this drug should be continued through the current study, while closely watching the situation.</li> </ul>



## Planned R&D topics for 2005

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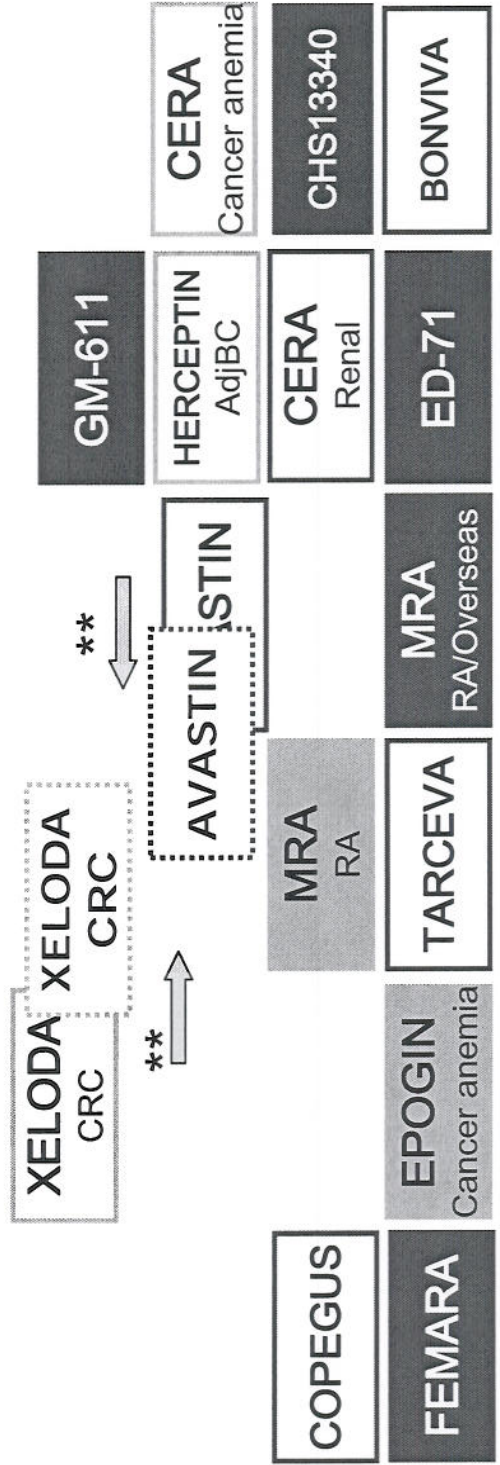
- EPOCH: file for chemotherapy-induced anemia
  - R435: start Safety Confirmation Study for colorectal cancer  
: start preparation for filing
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- \* CAL: completed phase II for bone metastases; *future plan to be decided*
  - \* R340: filing for expanded indication of colorectal cancer; *how to proceed to be discussed with the authority*





# Major Projected Submissions (Post PoC\*)

Filings planned each year



Filed 2005 2006 2007 2008-2010 2011-

NMEs 
  Additional Indications 
  licensed from Roche

\* PoC = Proof of Concept: (Verifies that the development concept shows efficacy in humans)  
 \*\* To be consulted with the authority





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