

# Overview of Development Pipeline

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# Projects under Development (as of July 23, 2009)

	Phase I	Phase II	Phase III	Filed
Oncology	<b>TP300 - CRC</b> <b>CIF/R7167 - solid tumor</b> <b>CKI27/R7304</b> - solid tumor <b>GC33 - liver cancer</b> R7159/GA101 - NHL R1507(hIGF-1R) - solid tumor	<b>MRA/Actemra - MM</b> R435/Avastin - BC R1415/Tarceva - PC	<b>EPOCH/Epogin - CIA</b> R340/Xeloda - GC R435/Avastin - aCC - GC - aBC - Glioblastoma★ R597/Herceptin - GC R1273/pertuzumab - BC	R340/Xeloda - CRC R435/Avastin - NSCLC
Bone & Joint		<b>MRA/Actemra - RA(sc)</b> R484/Bonviva(oral) - osteoporosis	<b>MRA/Actemra (overseas)</b> - sJIA <b>ED-71 - osteoporosis</b> R1594/ocrelizumab - RA R484/Bonviva(inj) - osteoporosis	<b>MRA/Actemra - RA (US)</b>
Renal				R744/Mircera - renal anemia★
Others	<b>NA808 - HCV</b> <b>MRA/Actemra (overseas)</b> - Castleman's disease <b>MRA/Actemra - SLE</b> R1579/(DPPIV) - diabetes	<b>CSG452/R7201</b> - diabetes <b>GM-611 - gastroparesis</b> <b>MRA/Actemra</b> - Crohn's disease R1583(GLP-1) - diabetes★ R1678/(GlyT-1) - schizophrenia	R442/Pegasys - HBV R442+R964/Pegasys + Copegus - cirrhosis	<b>EPOCH/Epogin</b> - autologous blood transfusion

Letters in purple: in-house projects

★ Projects with advances in stages since Apr 24, 2009

# Development Status – Oncology (1)

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In-house

## Epogin (epoetin beta)

Chemotherapy-induced anemia: primary endpoint achieved in phase 3 trial

- ➡ Theoretical transfusion rate significantly reduced
- ➡ Plan to file for approval with the phase 3 data by end of 2009

In-house

## TP300 (topoisomerase I inhibitor)

Solid tumor: phase 1 status overseas, phase 1 data presented at ASCO

# Development Status – Oncology (2)

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## Avastin (bevacizumab)

Non-small cell lung cancer: filed in November 2008, review on-going

- ➡ Filed with domestic phase 2 data & overseas phase 3 data
- ➡ Designated for a priority review

Breast cancer: plan to file by end of 2009

- ➡ To be filed with with domestic phase 2 data & overseas phase 3 data

Adjuvant colon cancer: global AVANT study on-going

- ➡ US C-08 study did not meet the primary endpoint
- ➡ Results expected in 2010 for AVANT study

Glioblastoma: decided to join the global phase 3 study

- ➡ First patient dosing expected by end of 2009 in Japan

## Development Status – Oncology (3)

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Roche  
Product

### Tarceva (erlotinib)

Pancreatic cancer: To be filed by end of 2009 with domestic phase 2 data & overseas phase 3 data

Roche  
Product

### Herceptin (trastuzumab)

Gastric cancer: positive results from ToGA study

- ➡ ToGA results presented at ASCO (primary endpoint achieved)
- ➡ Plan to file for approval in 2010

Roche  
Product

### Xeloda (capecitabine)

Colorectal cancer: filed in February 2008, review on-going

Gastric cancer: comadministered in ToGA and AVAGAST studies

- ➡ Combination with Herceptin (ToGA) or Avastin (AVAGAST)
- ➡ Plan to file in 2010 and 2011, with above studies

# Development Status – Bone & Joints

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In-house

## Actemra (tocilizumab)

### Rheumatoid Arthritis: Good results also for 2 year analysis of LITHE

- ➡ 2 year data of LITHE demonstrated continued inhibition of structural joint damage and high remission rate observed in 1 year analysis
- ➡ Data presented at EULAR
  - Long term extension studies, GROWTH95&96 data demonstrates up to 56% remission in more than 2 years treatment, regardless of previous treatment or duration of disease
  - 1 year data from LITHE demonstrates inhibition of structural joint damage and high remission rate

In-house

## ED-71 (eldecalcitol)

Active Vitamin D3 Derivative; co-development with Taisho Pharmaceutical

### Osteoporosis: To be file by end of 2009 with positive phase 3 data

- ➡ Significantly reduced the incidence of new vertebral fractures

# Development Status – Renal & Others

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Roche  
Product

**C.E.R.A.** (continuous erythropoietin receptor activator)

Renal anemia: Filed in July 2009

➡ Filed for anemia in hemo-dialysis, peritoneal-dialysis and pre-dialysis patients, utilizing data from six domestic phase 3 studies

Roche  
Product

**R1583/ITM-077** (taspoglutide)

GLP-1 analogue; co-development with Teijin

Type II diabetes: started domestic phase 2 study

Roche  
Product

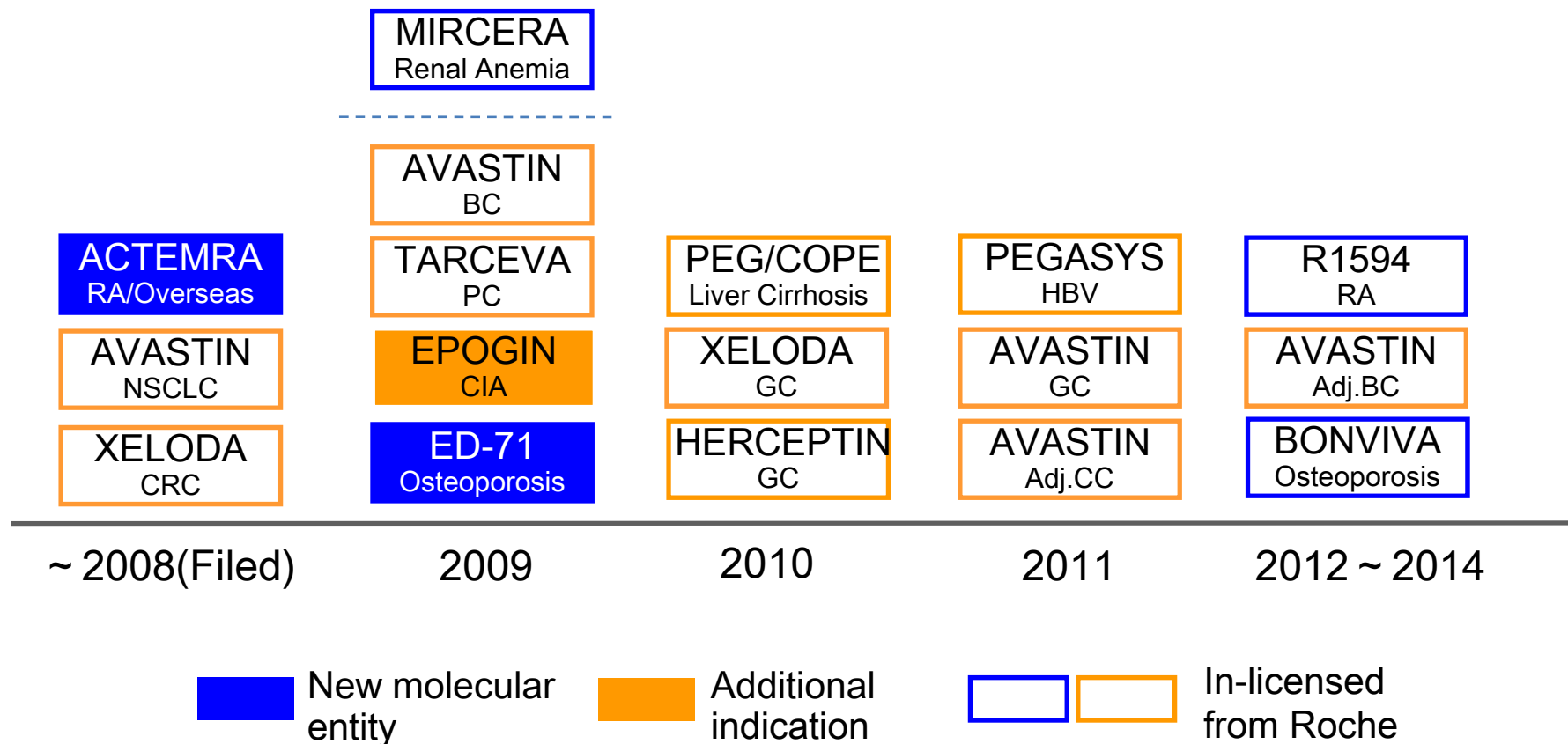
**Tamiflu Dry Syrup 3%**

Anti-influenza virus: partial amendment approved in July 2009

➡ Shelf-life extended to three years from previous two years; change in site of manufacturing

# Projected Submissions

Filings planned each year





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