# Overview of Development Pipeline

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

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

Letters in purple: in-house projects
★Projects with advances in stages since Apr 24, 2009

# Development Status – Oncology (1)

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)

Roche Product

## 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)

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

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

Roche Product

## C.E.R.A. (continuous erythropoetin 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**

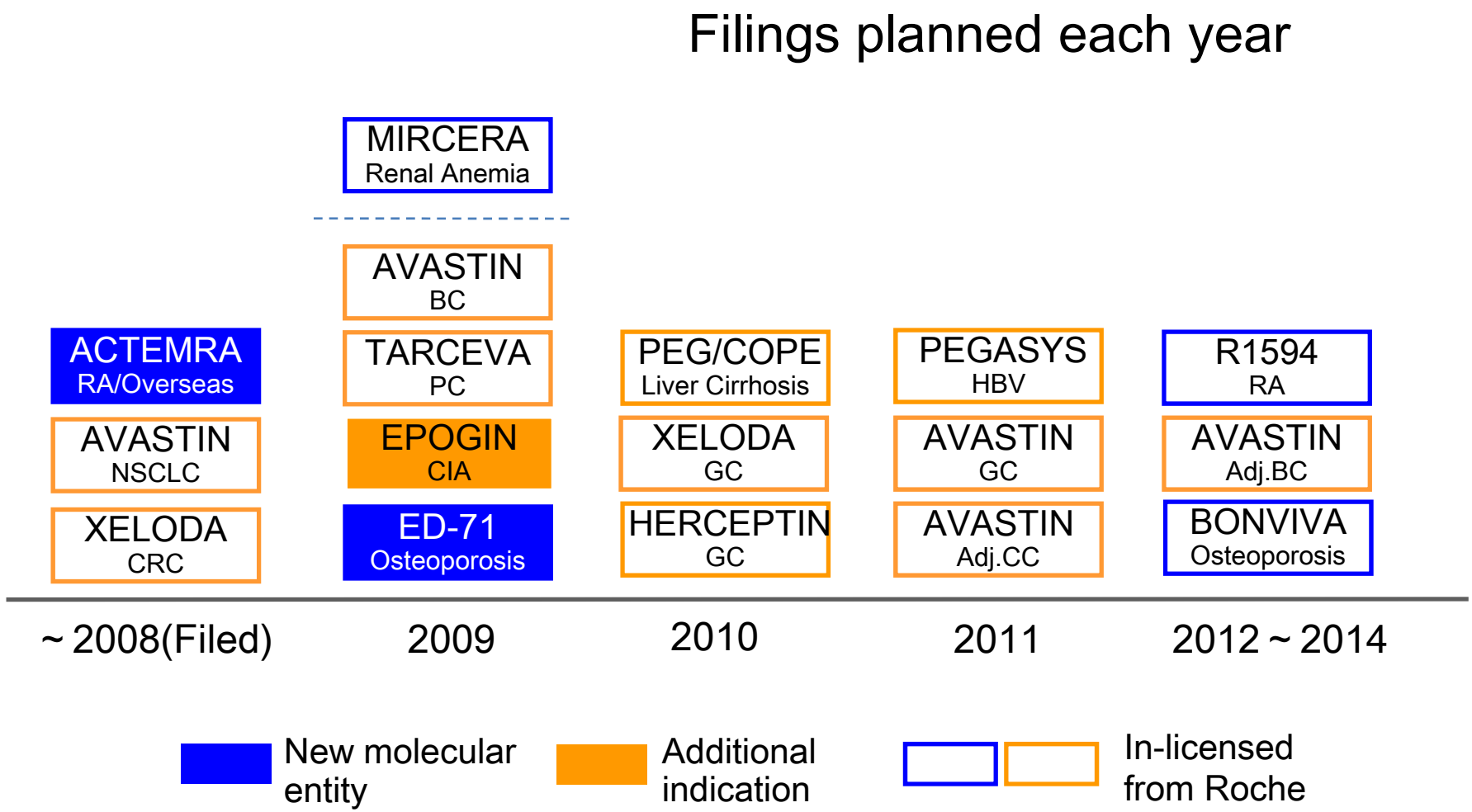
Roche Product

## 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



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