Roche to present new data on medicines for autoimmune diseases and severe inflammatory disorders at the 2016 ACR/ARHP Annual Meeting

- 15 oral presentations from 17 abstracts across six autoimmune conditions
- First presentation of Actemra/RoActemra data from GiACTA - the largest ever clinical trial in people with giant cell arteritis (GCA), a condition for which there has been no approved therapy in more than 50 years
- New data from two studies investigating cardiovascular outcomes for people with rheumatoid arthritis (RA) treated with Actemra/RoActemra

Roche today announced that new data from Actemra®/RoActemra® and Rituxan®/MabThera® will be presented during the 2016 American College of Rheumatology (ACR) and Association for Rheumatology Health Professionals (ARHP) Annual Meeting from 11-16 November in Washington, D.C, US. These data add to the significant body of evidence for Actemra®/RoActemra® and Rituxan®/MabThera® in RA and other serious immune-mediated conditions including GCA, systemic sclerosis (SSc), Takayasu arteritis, granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA).

“Advances in our scientific understanding of immune pathways are guiding the development of potential new treatments for severe autoimmune conditions,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “Building on our more than a decade of experience in providing treatment options for people suffering from rheumatologic conditions, we look forward to sharing new data at this year’s ACR/ARHP meeting.”

At this meeting, key presentations from Roche will include: the first efficacy and safety results from GiACTA – a study investigating Actemra/RoActemra in GCA, an often chronic, potentially life-threatening autoimmune condition; ENTRACTE, a Phase IV study in patients with RA evaluating the risk of cardiovascular (CV) events with Actemra/RoActemra in comparison to etanercept; a real world data analysis of CV outcomes in RA patients who switched from another biologic agent to either Actemra/RoActemra or a
tumour necrosis factor inhibitor (TNFi); plus further insights into the use of Actemra/RoActemra in SSc. Additionally, treatment insights from Rituxan/MabThera in RA and GPA/MPA will also be presented.

**Overview of key oral and poster presentations featuring Roche medicines at the 2016 ACR/ARHP Annual Meeting.** Please note that in accordance with the meeting’s policy, all abstract data is strictly embargoed until 12 November 2016, 4.30 PM ET.

<table>
<thead>
<tr>
<th>Presentation title</th>
<th>Abstract number / presentation timings (all times listed are Eastern Standard Time)</th>
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<tbody>
<tr>
<td><strong>Tocilizumab studies</strong></td>
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| Efficacy and Safety of Tocilizumab in Patients with Giant Cell Arteritis: Primary and Secondary Outcomes from a Phase 3, Randomised, Double-Blind, Placebo-Controlled Trial *(Stone J, et al.)* | **Type: Oral presentation** Abstact ID: 911  
Sun, 13 November  
11.00 AM – 12.30 PM |
| Safety and Efficacy of Subcutaneous Tocilizumab in Early Systemic Sclerosis: Results from the Open-Label Period of a Phase 2 Randomised, Controlled Trial *(Khanna D, et al.)* | **Type: Oral presentation**  
Abstract ID: 969  
Sun, 13 November  
02.30 – 04.00 PM |
| Comparative Cardiovascular Safety of Tocilizumab Vs Etanercept in Rheumatoid Arthritis: Results of a Randomised, Parallel-Group, Multicentre, Noninferiority, Phase 4 Clinical Trial *(Giles JT, et al.)* | **Type: Oral presentation**  
Abstract ID: 3L  
Tues, 15 November  
04.30 – 06.00 PM |
| Efficacy and Safety of Tocilizumab in Patients with Refractory Takayasu Arteritis: Results from a Randomised, Double-Blind, Placebo-Controlled, Phase 3 Trial in Japan *(Nakaoka Y, et al.)* | **Type: Oral presentation**  
Abstract ID: 976  
Sun, 13 November  
02.30 – 04.00 PM |
| Comparative Effectiveness of Tocilizumab Monotherapy with Tumour Necrosis Factor Inhibitors in Combination with Methotrexate in Patients with Rheumatoid Arthritis and Prior Exposure to Tumour Necrosis Factor Inhibitors *(Harrold L, et al.)* | **Type: Poster presentation**  
Abstract ID: 1596  
Mon, 14 November  
09.00 – 11.00 AM |
<table>
<thead>
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<th>Title</th>
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<tr>
<td>Cardiovascular Safety of Tocilizumab Versus Tumour Necrosis Factor Inhibitors in Patients with Rheumatoid Arthritis (Kim SC, et al.)</td>
<td>Poster presentation</td>
<td>2611</td>
<td>Tue, 15 November 09.00 – 11.00 AM</td>
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<td>Methotrexate Adherence in an Online Network of Patients with Rheumatoid Arthritis (Katic B, et al.)</td>
<td>Poster presentation</td>
<td>2532</td>
<td>Tue, 15 November 09.00 – 11.00 AM</td>
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<td>Patient-Reported Outcomes in Two Randomised, Controlled Trials (RCTs) in Patients with Rheumatoid Arthritis (RA) Treated with Tocilizumab (TCZ) Monotherapy Compared with Methotrexate (MTX) or Adalimumab (ADA) (Strand V, et al.)</td>
<td>Poster presentation</td>
<td>2515</td>
<td>Tue, 15 November 09.00 – 11.00 AM</td>
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<td><strong>Rituximab studies</strong></td>
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<td>Clinical and Serologic Variables Associated with Renal Response Among Lupus Nephritis Phase III Trial Patients Treated with Standard of Care Immunosuppression (Cascino MD, et al.)</td>
<td>Oral presentation</td>
<td>965</td>
<td>Sun, 13 November 2.30 – 4.00 PM</td>
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<tr>
<td>Factors Associated with Glucocorticoid Exposure in ANCA-Associated Vasculitis (Cascino MD, et al.)</td>
<td>Poster presentation</td>
<td>1930</td>
<td>Mon, 14 November 09.00 – 11.00 AM</td>
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<td>Impact of Rituximab on Patient-Reported Outcomes in Patients With Rheumatoid Arthritis From the US Corrona Registry (Harrold LR, et al.)</td>
<td>Poster presentation</td>
<td>1580</td>
<td>Mon, 14 November 09.00 – 11.00 AM</td>
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**About Roche in Immunology**

The Roche Group’s immunology medicines include: Actemra®/RoActemra® (tocilizumab) for rheumatoid arthritis and juvenile idiopathic arthritis; Rituxan®/MabThera® (rituximab) for rheumatoid arthritis granulomatosis with polyangiitis and microscopic polyangiitis; Xolair® (omalizumab) in allergic asthma; Pulmozyme® (dornase alfa) for cystic fibrosis; and Esbriet® (pirfenidone) for idiopathic pulmonary fibrosis. Roche’s immunology pipeline includes: RG7625, a cathepsin S antagonist; RG6125, a monoclonal antibody...
targeting cadherin-11; RG7845 (GDC-0853), a novel Bruton’s tyrosine kinase (BTK) inhibitor; obinutuzumab for lupus nephritis and hypersensitised patients with end-stage renal disease; etrolizumab for ulcerative colitis and Crohn’s disease; and lebrikizumab in a number of respiratory conditions and atopic dermatitis.

Roche in Immunology:
http://www.roche.com/research_and_development/what_we_are_working_on/immunology.htm

About Roche
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives. Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry eight years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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