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## **Roche and Biogen Idec decide to suspend Ocrelizumab treatment - Rheumatoid Arthritis development programme on hold**

**Future of the Ocrelizumab RA clinical programme under evaluation**

Roche and Biogen Idec announced today their decision to suspend Ocrelizumab treatment of patients in the Rheumatoid Arthritis (RA) programme. The decision follows the recommendation of the independent Ocrelizumab RA & Lupus Data and Safety Monitoring Board (DSMB) based on their assessment of the studies in RA (SCRIPT, FEATURE, FILM and STAGE) and lupus (BELONG and BEGIN).

The DSMB concluded that the safety risk outweighs the benefits observed in these specific patient populations at this time. The DSMB review detected an infection related safety signal which included serious and opportunistic infections, some of which were fatal.

As previously announced, the FILM study in MTX-naïve RA patients was placed on clinical hold following an assessment of benefit to risk in this specific RA patient population. In addition, the BELONG study in lupus nephritis patients was previously halted due to serious and opportunistic infection signals.

"Patient safety is of the utmost importance in all of our drug development programmes. In light of the DSMB recommendations we have decided to suspend Ocrelizumab treatment in the RA clinical development programme ." said Hal Barron, MD Executive Vice President and Chief Medical Officer at Roche.

The SCRIPT trial in patients who inadequately responded to one or more TNF antagonists and the FILM trial remain blinded. A detailed analysis of all of the data will be conducted to help further inform the future of the Ocrelizumab RA clinical programme.

Ocrelizumab is also being evaluated for Relapsing Remitting Multiple Sclerosis (RRMS). The treatment in the Ocrelizumab RRMS Phase II study is on-going at this time.

### **About Biogen Idec**

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing, and commercialization of innovative therapies. Patients worldwide benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis, and rheumatoid arthritis. For product labeling, press releases and additional information about the company, please visit <http://www.biogenidec.com>.

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### **Roche Group Media Relations**

Phone: +41 -61 688 8888 / e-mail: [basel.mediaoffice@roche.com](mailto:basel.mediaoffice@roche.com)

- Alexander Klauser
- Martina Rupp
- Claudia Schmitt
- Nina Schwab-Hautzinger