



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 February 2012
EMA/807846/2011
Human Medicines Development and Evaluation

Addendum to public declaration of interests and confidentiality undertaking of the European network of paediatric research at the European Medicines Agency (Enpr-EMA) members relating to research interests

Please sign and date. If the document is completed by hand, please ensure that the information required is clearly readable (capital letters).

Public Declaration of Research Interests

I, Dr. Nicolino Ruperto

Nationality: Italian

**Organisation/company: Istituto di Ricovero e Cura a Carattere Scientifico Giannina Gaslini
PEDIATRIA II, REUMATOLOGIA**

**PEDIATRIC RHEUMATOLOGY INTERNATIONAL TRIALS ORGANISATION (PRINTO at
www.printo.it or www.pediatric-rheumatology.printo.it)**

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do hereby declare on my honor that, to the best of my knowledge, the only research interests I have are those listed below (Please tick all boxes):



Current research interests and/or research completed in the past 12 months.

Please use additional pages if required by copying and pasting the text-boxes and check-boxes below. You will need to **protect the form** to enable proper use of boxes (fields); to do this you should view toolbar called "Forms", then click on the locking symbol named "Protect Form", and only then start typing entries into boxes.

Research title: A 12-week randomized, double blind, placebo-controlled, parallel group, 2-arm study to evaluate the efficacy and safety of tocilizumab in patients with active systemic juvenile idiopathic arthritis (sJIA); with a 92-week single arm open-label extension to examine the long term use of tocilizumab

Category: (Please tick all that apply)

Basic / translational	Non-clinical	Clinical	Epidemiology	Methodological	Pharmacovigilance	Education/ Training
☐	☐	☒	☐	☐	☐	☐

Funding: (Please tick all that apply)

Industry	European Commission	Medical research charity (not for profit organization):	National grant	International grant	Other (if so please describe)
☒	☐	☐	☐	☐	☐

Research title: A 24 WEEK RANDOMIZED DOUBLE-BLIND, PLACEBO CONTROLLED WITHDRAWAL TRIAL WITH A 16 WEEK OPEN LABEL LEAD-IN PHASE, AND 64 WEEK OPEN LABEL FOLLOW-UP, TO EVALUATE THE EFFICACY AND SAFETY OF TOCILIZUMAB IN PATIENTS WITH ACTIVE POLYARTICULAR-COURSE JUVENILE IDIOPATHIC ARTHRITIS

Category: (Please tick all that apply)

Basic / translational	Non-clinical	Clinical	Epidemiology	Methodological	Pharmacovigilance	Education/ Training
☐	☐	☒	☐	☐	☐	☐

Funding: (Please tick all that apply)

Industry	European Commission	Medical research charity (not for profit organization):	National grant	International grant	Other (if so please describe)
☒	☐	☐	☐	☐	☐

Research title: A randomized, double-blind, placebo controlled, single dose study to assess the initial efficacy of canakinumab (ACZ885) with respect to the adapted ACR Pediatric 30 criteria in patients with Systemic Juvenile Idiopathic Arthritis (SJIA) and active systemic manifestations;
A randomized, double-blind, placebo controlled, withdrawal study of flare prevention of canakinumab (ACZ885) in patients with Systemic Juvenile Idiopathic Arthritis (SJIA) and active systemic manifestations;
An open-label extension study of canakinumab (ACZ885) in patients with Systemic Juvenile Idiopathic Arthritis (SJIA) and active systemic manifestations.

Category: (Please tick all that apply)

Basic / translational	Non-clinical	Clinical	Epidemiology	Methodological	Pharmacovigilance	Education/ Training
☐	☐	☒	☐	☐	☐	☐

Funding: (Please tick all that apply)

Industry	European Commission	Medical research charity (not for profit organization):	National grant	International grant	Other (if so please describe)
☒	☐	☐	☐	☐	☐

Research title: A Multicenter, Double Blind, Randomized-Withdrawal Trial of Subcutaneous Golimumab, a Human Anti-TNF α Antibody, in Pediatric Subjects with Active Polyarticular Course Juvenile Idiopathic Arthritis (JIA) Despite Methotrexate Therapy

Category: (Please tick all that apply)

Basic / translational	Non-clinical	Clinical	Epidemiology	Methodological	Pharmacovigilance	Education/ Training
☐	☐	☒	☐	☐	☐	☐

Funding: (Please tick all that apply)

Industry	European Commission	Medical research charity (not for profit organization):	National grant	International grant	Other (if so please describe)
☒	☐	☐	☐	☐	☐

Research title: An Observational Registry of Abatacept in Patients with Juvenile Idiopathic Arthritis

Category: (Please tick all that apply)

Basic / translational	Non-clinical	Clinical	Epidemiology	Methodological	Pharmacovigilance	Education/ Training
☐	☐	☒	☒	☐	☒	☐

Funding: (Please tick all that apply)

Industry	European Commission	Medical research charity (not for profit organization):	National grant	International grant	Other (if so please describe)
☒	☐	☐	☐	☐	☐

Research title: PHARMACOVIGILANCE IN JUVENILE IDIOPATHIC ARTHRITIS PATIENTS (PHARMACHILD) TREATED WITH BIOLOGIC AGENTS AND/OR METHOTREXATE (EU GRANT NR. 260353)

Category: (Please tick all that apply)

Basic / translational	Non-clinical	Clinical	Epidemiology	Methodological	Pharmacovigilance	Education/ Training
☐	☐	☒	☐	☐	☒	☐

Funding: (Please tick all that apply)

Industry	European Commission	Medical research charity (not for profit organization):	National grant	International grant	Other (if so please describe)
☐	☒	☐	☐	☐	☐

Research title: FIVE-YEAR SINGLE-BLIND, PHASE III EFFECTIVENESS RANDOMISED ACTIVELY CONTROLLED CLINICAL TRIAL IN NEW ONSET JUVENILE DERMATOMYOSITIS: PREDNISONE VERSUS PREDNISONE PLUS CYCLOSPORINE A VERSUS PREDNISONE PLUS METHOTREXATE

Category: (Please tick all that apply)

Basic / translational	Non-clinical	Clinical	Epidemiology	Methodological	Pharmacovigilance	Education/ Training
☐	☐	☒	☐	☐	☐	☐

Funding: (Please tick all that apply)

Industry	European Commission	Medical research charity (not for profit organization):	National grant	International grant	Other (if so please describe)
☐	☐	☐	☐	☐	☒ Italian Agency for Drug (Agenzia Italiana del Farmaco-AIFA)

Research title: A multinational study of the EPidemiology, treatment and Outcome of Childhood Arthritis (EPOCA)

Category: (Please tick all that apply)

Basic / translational	Non-clinical	Clinical	Epidemiology	Methodological	Pharmacovigilance	Education/ Training
☐	☐	☒	☒	☐	☐	☐

Funding: (Please tick all that apply)

Industry	European Commission	Medical research charity (not for profit organization):	National grant	International grant	Other (if so please describe)
☐	☐	☒	☐	☐	☐

Research title: The PReS Autoinflammatory Diseases' Working Group, in collaboration with PRINTO, set up a web-based international registry for Autoinflammatory diseases (Eurofever project)

Category: (Please tick all that apply)

Basic / translational	Non-clinical	Clinical	Epidemiology	Methodological	Pharmacovigilance	Education/ Training
☐	☐	☒	☒	☐	☐	☐

Funding: (Please tick all that apply)

Industry	European Commission	Medical research charity (not for profit organization):	National grant	International grant	Other (if so please describe)
☐	☒	☐	☐	☐	☐

Research title: Anti-Biopharmaceutical Immunization (ABIRISK): Prediction and analysis of clinical relevance to minimize the risk

Category: (Please tick all that apply)

Basic / translational	Non-clinical	Clinical	Epidemiology	Methodological	Pharmacovigilance	Education/ Training
☒	☐	☒	☐	☐	☐	☐

Funding: (Please tick all that apply)

Industry	European Commission	Medical research charity (not for profit organization):	National grant	International grant	Other (if so please describe)
☐	☒	☐	☐	☐	☐

Research title: Single Hub and Access point for paediatric Rheumatology in Europe

Category: (Please tick all that apply)

Basic / translational	Non-clinical	Clinical	Epidemiology	Methodological	Pharmacovigilance	Education/ Training
☐	☐	☒	☐	☐	☐	☒

Funding: (Please tick all that apply)

Industry	European Commission	Medical research charity (not for profit organization):	National grant	International grant	Other (if so please describe)
☐	☒	☐	☐	☐	☐

Scientific publications: (Most relevant in past 3 years; maximum 5)

1. Foell D, Wulffraat N, Wedderburn LR, Wittkowski H, Frosch M, Gerß J, Stanevicha V, Mihaylova D, Ferriani V, Kanakoudi Tsakalidou F, Foeldvari I, Cuttica R, Gonzalez B, Ravelli A, Khubchandani R, Oliveira S, Armbrust W, Garay S, Vojinovic J, Norambuena X, Gamir ML, García-Consuegra J, Lepore L, Susic G, Corona F, Dolezalova P, Pistorio A, Martini A, Ruperto N, Roth J, for the Paediatric Rheumatology International Trials Organization (PRINTO). Methotrexate withdrawal at 6 vs 12 months in juvenile idiopathic arthritis in remission: a randomized clinical trial. JAMA 2010;303(13):1266-1273.
2. Ruperto N, Lovell DJ, Quartier P, Paz E, Rubio-Pérez N, Silva CA, Abud-Mendoza C, Burgos-Vargas R, Gerloni G, Melo-Gomes JA, Saad-Magalhães C, Chavez J, Huemer C, Kivitz A, Blanco FJ, Foeldvari I, Hofer M, Horneff G, Huppertz HI, Job Deslandre C, Loy A, Minden K, Punaro M, Flores Nunez A, Sigal LH, Block AJ, Nys M, Martini A, Giannini EH, for the Paediatric Rheumatology International Trials Organization (PRINTO) and the Pediatric Rheumatology Collaborative Study Group (PRCSG). Long-Term Safety and Efficacy of Abatacept in Children with Juvenile Idiopathic Arthritis. Arthritis Rheum 2010;62(6):1792-1802.
3. Ruperto N, Giannini EH, Pistorio A, Brunner HI, Martini A, Lovell DJ. Is it time to move to active comparator trials in juvenile idiopathic arthritis? A review of current study designs. Arthritis Rheum 2010;62:3131-3139.
4. Hasija R, Pistorio A, Ravelli A, Demirkaya E, Khubchandani R, Guseinova D, Malattia C, Canhao H, Harel L, Foell D, Wouters C, De Cunto C, Huemer C, Kimura Y, Mangge H, Minetti C, Nordal EB, Philippet P, Garozzo R, Martini A, Ruperto N, for the Paediatric Rheumatology International Trials Organisation (PRINTO). Therapeutic approaches in the treatment of juvenile

dermatomyositis in patients with recent-onset disease and in those experiencing disease flare. An international multicenter PRINTO study. Arthritis Rheum 2011;63(10):3142-3152.

5. Ruperto N, Quartier P, Wulffraat N, Woo P, Ravelli A, Mouy R, Bader-Meunier B, Vastert SJ, Nosedà E, D'Ambrosio D, Lecot J, Chakraborty A, Martini A, Chioato A for the Paediatric Rheumatology International Clinical Trials Organisation (PRINTO). A phase II study to evaluate dosing and preliminary safety and efficacy of canakinumab in systemic juvenile idiopathic arthritis with active systemic features. Arthritis Rheum 2012;64(2):557-567.



Signature:

..... **Date (DD/MM/YY):**

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