WEDNESDAY, 13 JUNE 2018

New drugs – new perspectives: clinical and regulatory issues concerning biosimilars

SP0024 AN UP-DATE ON BIOSIMILARS

T.K. Kvien. Department of Rheumatology, Diakonhjemmet Hospital, Oslo, Norway

Biosimilars represent a new opportunity for lowering the cost of treatment with biological disease-modifying antirheumatic drugs (bDMARDs). Studies have demonstrated large inequities in the access to bDMARDs across countries and this inequity is related to economic parameters such as gross domestic product. Thus, reduced costs of bDMARDs should potentially lead to better treatment for more patients, especially in countries with low economy.

The regulatory agencies in Europe and in US have set up strict guidelines for approval of biosimilars which include extensive pre-clinical examinations (structure and functional characteristics) but less clinical data than for an originator product. The clinical part of this comparability exercise focuses on efficacy, safety, pharmacokinetics as well as immunogenicity.

Three biosimilars to adalimumab have also been approved but the patent of the reference product has not yet expired (expected to occur October 2018). (expected to occur October 2018). It is a growing acceptance about the use of these biosimilars, also in extrapolated indications when treatment are started or changed for medical reasons. Most rheumatologists will consider the biosimilars on the same level as originator products in these situations.

However, replacing an originator product by a biosimilar is more controversial, but is important because of the large cost-savings. Switching evidence is available from four different types of studies which will be discussed:

- Extension of phase 3 RCTs
- Switching within RCTs
- Real life data (eg from DANBIO)
- Randomising patients on stable long-term treatment

In the NOR-SWITCH trial – totally funded by the Norwegian government – 482 patients on stable treatment with the reference product infliximab across 6 indications (RA, SpA, PsA, UC, CD, PsO) were randomised to continued treatment with the reference product or switch to the biosimilar CT-P13; Jørgensen KK et al. *Lancet* 2017;389:2304–2316). The primary endpoint was occurrence of disease worsening, defined by the disease-specific composite measures or clinically significant worsening leading to a major change in treatment. Overall, disease worsening occurred in 26.2% of patients who continued treatment with the originator infliximab and in 29.6% of patients who switched to CT-P13. The adjusted treatment difference (95% CI) was –4.4% (–12.7–3.9) which was within the prespecified non-inferiority margin of –15%. The occurrence of adverse events, including infusion reactions, was similar across both groups. There were no differences between the two groups in secondary endpoints, including time to study drug discontinuation, remission rates, CRP levels, anti-drug antibody formation and drug trough levels. The extension study (not yet published) showed that switching from originator to biosimilar was not inferior to continued treatment with the biosimilar.

In conclusion, the NOR-SWITCH study demonstrated that switching to CT-P13 was not inferior to continued treatment with originator infliximab, adding to the increasing real-world evidence that switching from originator to biosimilar bDMARD is safe and efficacious.

Disclosure of Interest: T. Kvien Consultant for: AbbVie, Biogen, BMS, Boehringer Ingelheim, Celgene, Celltrion, Eli Lilly, Epirus, Hospira, Merck-Serono, MSD, Mundipharma, Novartis, Oktal, Orion Pharma, Hospira/Pfizer, Roche, Sanofi and UCB

DOI: 10.1136/annrheumdis-2018-eular.7858

SP0025 SHARED DECISION MAKING IN SWITCHING TO BIOSIMILARS

T. French. Rheumatology, University Hospitals Bristol NHS Foundation Trust, Bristol, UK

This presentation will focus on the speaker's experience of switching patients who are on an originator biologic therapy to a biosimilar, using a shared decision making approach. It will initially explore what constitutes shared decision making, why it is important when switching to biosimilars and the benefits of this approach.

The speaker will discuss how this change in therapy was achieved in practice when switching patients to both intravenous and subcutaneous biosimilars. There

will be a focus on the patient consultation itself, recognising patient anxiety and an exploration of why some patients declined to switch.

The speaker will share how loss of efficacy to the biosimilar was managed, and how this influenced the shared decision making approach.

Clinician's concerns will also be considered, specifically the inability to maintain pharmacovigilance (in not having sufficient nursing resources to add patients who had switched to a biosimilar to a national register). This is relevant to shared decision making as providing evidence and reassurance to patients regarding safety of biosimilars relies on this data collection.

The guidance referred to in this presentation is from NHS England, National Institute for Health and Care Excellence and the British Society for Rheumatology, so it has a UK focus. However, the main themes of the talk should be relevant to all audience members as it considers the opposing pressures on Rheumatology nurses to be change agents and make cost savings in implementing this switch to biosimilars. Whilst nurses also need to act as the patient advocate in ensuring shared decision making is a reality: that a face-to-face consultation takes place and that the patient can decline to switch and not feel penalised. The speaker will reflect on how the trust in her relationship with her patients was tested by this experience.

The main recommendation from this presentation is that rheumatology teams need to be proactive in managing this change and securing extra funding for nursing or pharmacy support. This 'invest to save' approach will enable appropriate consultation with patients to allow them to give informed consent to switch their therapy and feel supported whilst this switch takes place. It also enables maximum cost savings by ensuring the switch occurs quickly.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.7835

SP0026 BIOSIMILARS – THE CHANGING VIEWS OF PARE'S MEMBER ORGANISATIONS

D. Wiek. EULAR PARE, Huenxe, Germany

After EULAR PARE's position paper "Biosimilars – what do patients need to consider" published in November 2015 more biosimilars for rheumatic diseases have been approved by EMA (European Medicine Agency), have entered the market in different European countries and more biosimilars will be marketed. New studies and data informing about the use of biosimilars, as well as feedback received from patient organisations and in particular from PARE organisations, have made it necessary to update PARE's 2015 position.

Biological therapies are enormous cost factors for the healthcare system and biological therapies have to be affordable, what is seen as difficult in various countries. But an optimal quality healthcare is enormously important for the individual patient (e.g. fewer sick days, less hospitalisation, less disabilities), prevents early retirement and thus saves costs and contributes to a country's economic and social system.

If so-called naïve patients should take a biologic, the less expensive biosimilar can be used, as long as there are no contraindications, the patient has been informed and the decision is based on a shared decision between rheumatologist and patient.

But transitioning users from an originator to a biosimilar is very controversial and seen critically by PARE's patient organisations. The talk will cover the changing views concerning extrapolation, one-time switch, multiple therapy switches, registries and the relevance of the application form for patients.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.7728

WEDNESDAY, 13 JUNE 2018

Don't delay, connect today!

SP0027 DON'T DELAY, CONNECT TODAY – IMPLEMENTATION OF THE EULAR CAMPAIGN IN ROMANIA

R. Ionescu. Department of Internal Medicine and Rheumatology, University of Medicine and Pharmacy "Carol Davila", Sf. Maria Hospital, Bucharest, Romania

Background 22% of the population in Europe currently has, or had experienced "long-term muscle, bone and joint problems".¹ Early referral to a rheumatologist for appropriate diagnosis and treatment prevent structural damage, disability and decrease mortality.²

Objectives: To launch a patient oriented campaign in Romania in order to increase awareness of rheumatic musculoskeletal diseases (RMDs) – early