

EULAR Congress News

An authorised publication of the European League Against Rheumatism



2018 congress reflects EULAR's continued efforts to advance the rheumatology community

Welcome to Amsterdam for the start of the 19th Annual EULAR European Congress of Rheumatology! We return to Amsterdam for the first time since the congress was held there in 2006, bringing together 14,000 participants from more than 120 countries in Europe and around the world. Amsterdam's magnificent ambiance of canals and canalside houses, galleries, astonishing museums, theatres, music, and culinary pleasures will again provide a unique background to facilitate interactions among patients, medical doctors, scientists, health professionals, and professionals representing the pharmaceutical industry.

We are grateful to have you with us, as your presence reflects an increasing and continued interest in what EULAR has to offer to the rheumatology community to advance scientific and clinical progress in the broad field of the rheumatic and musculoskeletal diseases.

This year, we received more than 5,050 abstract sub-

missions – the most ever. Overall, 51.9% were accepted for presentation and another 30.3% for publication. A total of 370 were accepted as oral presentations this year, and the congress features over 175 sessions and poster tours with more than 560 speakers. An additional 32 industry-supported scientific symposia will also be held.

All of these contributions also reflect the availability of increased information on the impact, burden, and cost of rheumatic and musculoskeletal diseases for the individual and society, and a significantly improved ability to diagnose and treat them (early). The incorporation of health professional and patient organisations within EULAR has been a unique stimulus for these advances. This intensive cooperation facilitates, for instance, the implementation of recommendations for management/standards of care of musculoskeletal disorders in daily practice – of which we have seen prime

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Prof. Johannes W.J. Bijlsma
EULAR President

Making the switch from originator biologic to biosimilar should be a shared decision

THE IMPORTANCE OF KEEPING the patient at the centre of the decision to switch from an originator biologic to a biosimilar, the need for more randomised, controlled trials on the safety of switching, and the vital role of pharmacovigilance are just some of the issues around biosimilars that are up for discussion this afternoon.

During the joint Health Professionals in Rheumatology and People with Arthritis/Rheumatism in Europe session, 'New drugs – new perspectives: clinical and regulatory issues concerning biosimilars,' Prof. Tore K. Kvien, head of the department of rheumatology at the

Diakonhjemmet Hospital in Oslo, will update delegates on the latest issues and evidence pertaining to the use of biosimilars.

Rheumatologists – at least in Europe – have generally accepted that biologic disease-modifying antirheumatic drugs (bDMARDs) and biosimilar DMARDs (bsDMARDs) should be considered equally when patients are commencing therapy or changing their treatment for medical reasons, Prof. Kvien said.

This is largely thanks to the rigorous regulatory approval process put in place by the European Medicines

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Second year of 'Don't Delay, Connect Today' seeks broader involvement in campaign

EULAR'S "DON'T DELAY, CONNECT TODAY" campaign is now in its second year after launching at last year's congress in Madrid, and speakers this year in Amsterdam are gearing up again to promote the campaign and describe its implementation so far. At a PARE session on Wednesday afternoon, Prof. Gerd R. Burmester, Prof. Tanja A. Stamm, Prof. Ruxandra Ionescu, and several other speakers will address different facets of the campaign.

Why we need the "Don't Delay, Connect Today" campaign

Prof. Burmester, Past President of EULAR and professor of medicine at Berlin's Charité University Clinic, will be speaking about the importance of the campaign, which "aims to raise awareness of the early diagnosis in preventing further damage for people with rheumatic and musculoskeletal diseases (RMDs) and to encourage timely access to evi-

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Congress activities highlight innovations and initiatives to improve patient care Continued from page 1

examples at our EULAR congresses.

The EULAR Congress 2018 in Amsterdam will offer a wide range of topics including clinical innovations, clinical translational research, and basic science. Furthermore, there will be meetings organised by People with Arthritis and Rheumatism in Europe (PARE), Health Professionals in Rheumatology (HPR), and by the healthcare industry. The WIN/HOT track for the busy clinician who wants an update on What is New and How to Treat the major rheumatic diseases has become a much praised highlight of the EULAR congress.

We will also learn about further results from our initiatives, the EULAR School of Rheumatology, the 'Don't Delay, Connect Today' campaign, and the launch of the EULAR Strategy 2018-2023.

Other crucial activities of the congress are the poster presentations and poster tours with their highly interactive exchanges among participants. Out of the 2,256 poster displays spread over 3 days, 435 posters will be explained in 45 themed poster tours. The Amsterdam event will further strengthen the reputation of the EULAR congress as a highly innovative and informative venue for clinical and translational researchers – not only within the different facets of our discipline (including inflammation, pain, bone, mechanical, and inflammatory disorders) but also learning from other relevant disciplines.

Today's Opening Plenary Session is now the first event of the congress. This session will bring you the latest EULAR news, focusing on the new strategy, and will honour the

winners of the best abstracts, the Stene Prize, new honorary members, the meritorious service award, and FOREUM awards, and will finish with a surprise TED talk. At this evening's Networking Platform event, there will be a presidential reception to further recognise and celebrate these award winners. In addition, we will recognise the many volunteers from our three pillars that put so much energy into EULAR.

And, as every year, an absolute highlight will be the EULAR Congress Dinner on Friday evening, held on the OceanDiva cruise ship. The OceanDiva will take us for a wonderful tour on the Amsterdam waters. Seats are very limited – rush to register and don't miss the unique opportunity of networking with colleagues and friends while enjoying the Netherlands at its best!

The EULAR congress has only been possible and come to be realised thanks to the untiring effort and support of all the EULAR members, including the Steering Group, the Scientific and Executive Committees, the EULAR Secretariat, and the MCI staff.

Amsterdam will provide an excellent platform for scientific and clinical exchanges, international collaborations, and renewal of friendships. We take great pleasure in welcoming medical doctors, patients, health professionals, and representatives of the pharmaceutical industry to EULAR 2018, and we hope that their stay in Amsterdam will be informative, educational and, last but not least, enjoyable.

Johannes W.J. Bijlsma
EULAR President

'Don't Delay' promotes health professionals' role in early diagnosis Continued from page 1

dence-based treatment."

Early diagnosis of RMDs is particularly important because most people receive a delayed diagnosis or no diagnosis at all, according to Prof. Burmester.

"Awareness of the importance of early diagnosis is limited amongst the general public, people with RMDs, and many doctors and health professionals in rheumatology (HPRs). For example, fibromyalgia remains undiagnosed in as many as three out of four people with the condition, and diagnosis time averages 5 years."

The EULAR campaign is also encouraging patients to see physicians soon after symptoms appear.

"EULAR hopes to encourage people to connect with their doctor when possible RMD symptoms appear, such as persistent joint and muscle pain, extreme fatigue, and stiffness. 'Don't Delay, Connect Today' also aims to help doctors and HPRs identify and treat diseases as early and accurately as possible."

By encouraging people to work together, positive steps can be taken to improve the lives of those living with RMDs, according to Prof. Burmester.

"By uniting everyone connected to the RMD community through 'Don't Delay, Connect Today,' we can work together to create significant positive change for people with RMDs. We want to ensure EULAR continues to place early diagnosis, access to treatment,

and the needs of RMD patients at the heart of everything we do."

How HPRs can support the campaign

HPRs can play a critical role in the early treatment of inflammatory conditions, said Prof.

Stamm of the Medical University of Vienna.

"HPRs refer patients early to medical specialists, if needed. Nurses, physiotherapists, and occupational therapists can identify patients with inflammatory conditions and refer them to rheumatologists early for timely and evidence-based care."

In fact, "physiotherapists can distinguish patients with early inflammatory arthritis from those without," with 89% concordance with a rheumatologists' subsequent diagnosis, she said. Occupational therapists also can decide whether patients require hospital admission or not in emergency care settings.

HPRs also play an important role in osteoarthritis care, according to Prof. Stamm, who is EULAR Vice President representing HPRs.

"HPRs provide timely, evidence-based care for osteoarthritis [that] reduces symptoms, comorbidity risk, and need for expensive surgical procedures."

Timely intervention with osteoarthritis is important because of the lack of medical drug treatments.



Prof. Stamm



Prof. Burmester



Prof. Ionescu

seek medical attention. Raising awareness includes providing information on signs and symptoms that may prompt individuals to seek a rheumatologist's advice.

The campaign is not only attempting to reach

Apart from drug interventions, one of the best ways to combat osteoarthritis is through healthy living and prevention both at home and in the workplace, she said.

"Occupational therapists, physiotherapists, and nurses apply ergonomic principles to make the work setting as healthy as possible and prevent RMDs and further comorbidities."

Implementation of the EULAR campaign in Romania

"The Don't Delay, Connect Today" campaign has been an important initiative in Romania, according to Prof. Ionescu, president of the Romanian Society of Rheumatology and General Secretary of EULAR.

"More than 600,000 people in Romania (3% of the total population), out of which 2,000 are children, suffer from inflammatory rheumatic diseases that are included in the RMDs category," she said.

The aim of the campaign in Romania has been similar to the aim of the campaign overall – to increase awareness of rheumatic diseases and encourage people to

Romanian citizens, but also those deciding on policy. Prof. Ionescu stated that individuals in the Health Ministry, Insurance House, and Parliament must be aware of the effects that rheumatic diseases can have on the population and the need to supply funding for medical care.

Prof. Ionescu will also discuss some of the major challenges the campaign has faced.

"[Some] major challenges we faced in clinical activity refer to insufficient funds from health care, insufficient number of rheumatologists, reluctance of patients to go early to rheumatologists. In most cases, the rheumatologist usually first sees the patient after he already has disabilities as a result of RMDs, making remission impossible, as the evolution of destructive lesions leads to an irreversible functional deficit."

PARE SESSION

'Don't Delay, Connect Today'

Wednesday 16:15 – 17:45

PARE Room

Zoledronic acid knee OA trial results coming in Plenary

The results of the randomised, multicentre zoledronic acid for osteoarthritis knee pain (ZAP2) trial will be released in a presentation at the Opening Plenary Abstract Session this afternoon. In a preview, the senior author warned that the enthusiasm generated by earlier studies will not be matched in the longer-term analysis.

“It may be that [zoledronic acid] still works in earlier disease, but this will require confirmation in other studies, some of which are underway,” reported Prof. Graeme Jones, professor of rheumatology and epidemiology at the Menzies Research Institute, Hobart, Australia.

The ZAP2 trial results have been long awaited. Interest in the potential of zoledronic acid to alter the natural history of knee osteoarthritis was generated by a placebo-controlled study that associated a single infusion of zoledronic acid with a reduction in bone marrow lesions (BML) on MRI imaging and pain scores at 6 months (*Ann Rheum Dis.* 2012;71:1322-8).

These findings attracted substantial interest because knee osteoarthritis is highly prevalent and imposes a substantial symptomatic burden, and because there have been to date no therapies associated with



Prof. Jones

disease-modifying activity in osteoarthritis, according to Prof. Jones. The ZAP2 study was launched to test the long-term benefits of zoledronic acid promised by the earlier study.

In ZAP2, 223 patients with knee osteoarthritis were randomised to receive an intravenous infusion of a 5-mg dose of zoledronic acid in 100 mL of saline or saline alone as a placebo. Entry criteria include an age of at least 50 years, the presence of BML on MRI, and significant knee pain. Severe knee osteoarthritis, defined by the Osteoarthritis Research Society International (OARSI)

as having joint-space narrowing of grade 3, was excluded.

The trial endpoints at 2 years included change from baseline in pain and function measured with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and BML as assessed with MRI.

At the Opening Plenary Abstract Session, Prof. Jones will present the details, but when asked to provide a preview of the outcome, he cautioned, “The enthusiasm that our initial trial generated has not been borne out in this larger, longer trial.”

This includes no significant differences between zoledronic acid and placebo at 2 years in baseline WOMAC scores for function and for pain and, perhaps most significantly from the point of view of disease-modifying activity, no significant difference in change in median BML size.

The study does not preclude any potential benefit from zoledronic acid. In one set of prespecified analyses, zoledronic acid was consistently more effective than placebo for pain control in patients without radiographic osteoarthritis, defined as a joint space narrowing grade of 0, according to Prof. Jones.

The mean age of the patients in this study was 62 years. About half of the enrollees were women.

Although zoledronic acid was well tolerated in this study, there were more adverse events in the zoledronic acid arm, particularly flu-like symptoms, musculoskeletal pain, and stiffness.

There is a theoretical potential for zoledronic acid and other bisphosphonates to preserve joint structure through their effects on bone resorption, but ZAP2 now joins other trials that have failed to confirm a disease-modifying effect for agents in this class. Prof. Jones said there are no extenuating factors that provide a basis for challenging the ZAP2 conclusion, which is that a single yearly 5-mg infusion of zoledronic acid has no significant disease-modifying effect on knee osteoarthritis. Further details will be provided at the Plenary Abstract Session.

Prof. Jones had no disclosures of interest to share.

ABSTRACT SESSION

Opening Plenary Abstract Session

Wednesday 16:15 – 17:45

Hall 7.1

Biomarker shows promise in distinguishing adult-onset Still's disease from sepsis

Japanese researchers have pinpointed a biomarker that could one day have the potential to speed up the diagnosis of adult-onset Still's disease, which has an average time of initial presentation to diagnosis of 4 months.

This afternoon, Dr. Tomohiro Koga of the rheumatology department at Nagasaki (Japan) University Hospital will describe his group's efforts in finding a serum biomarker – in this case, fibroblast growth factor 2 (FGF-2) – that could distinguish adult-onset Still's disease (AOSD) from sepsis.

People with AOSD often present to clinicians with nonspecific symptoms that can sometimes mimic other diseases, which makes the disease difficult for clinicians to diagnose, Dr. Koga noted in an interview.

“A number of conditions may present with combinations of features observed among AOSD patients, such as high fever, skin rash, arthritis, lymphadenopathy. ... The differential diagnosis of AOSD

is extensive, including a wide variety of infections, systemic autoimmune and inflammatory rheumatic diseases, malignancy, and adverse reactions to medications,” Dr. Koga explained.

This is further complicated by the presence of elevated acute phase responses, including C-reactive protein, erythrocyte sedimentation rate, leukocytosis, and abnormalities in liver enzymes in people with AOSD, which are also often seen in other rheumatic diseases and infections.

There are no established diagnostic criteria to aid the clinician in the diagnosis of AOSD, he said. Although there are established classification criteria – the Yamaguchi criteria – for the disease, they have lacked combined sensitivity and specificity to be useful for clinical diagnosis, Dr. Koga added.

Previous research has shown that



Dr. Koga

serum levels of interleukin (IL)-1beta, IL-6, and IL-18 are useful biomarkers for both diagnosis and disease evaluation among AOSD patients. However, because these cytokines are also elevated in other inflammatory diseases and severe infections, the research team set out to identify serum

biomarkers in people with AOSD that could be distinguishable from people with sepsis.

They measured the serum levels of 45 cytokines in 66 patients who were diagnosed by rheumatologists with AOSD based on the Yamaguchi classification criteria, 17 sepsis patients, and 133 age-matched controls.

Dr. Koga said that, as the researchers expected, a comprehensive cytokine analysis revealed that IL-18 was a reliable biomarker that could distinguish AOSD patients from sepsis patients. However, they were surprised to find that FGF-2 was a better marker than IL-18.

FGF-2 was able to distinguish AOSD patients from sepsis patients with the highest accuracy. At a cut-off value of 28.5 pg/mL, FGF-2 had a sensitivity of 100% and specificity of 88.2%.

“Like vascular endothelial growth factor (VEGF), FGF-2 is one of the most potent angiogenesis inducers, but the reason why it has a higher diagnostic potential than IL-18 is unclear,” Dr. Koga said.

Although measurement of the biomarker is not yet ready for the clinic, Dr. Koga said that he hopes further research will validate it, and it will become a clinically useful marker.

The researchers had no relevant financial disclosures.

ABSTRACT SESSION

Let's Improve Diagnosis and Treatment of Orphan Diseases

Wednesday 16:15 – 17:45

Room E106/E107

Cancer risk with tocilizumab in RA is largely reassuring

No increased risk of cancer could be found with the interleukin-6 blocker tocilizumab when compared with tumour necrosis factor inhibitors (TNFi) in rheumatoid arthritis (RA) patients who have failed previous treatment with different biologics, according to findings from a large study that will be presented this afternoon.

This issue is a common concern among both patients and physicians when choosing a treatment in everyday clinical practice, but there are limited data about the risk of malignancy in head-to-head comparisons of biologic agents for RA, according to first author Dr. Seoyoung C. Kim of Brigham and Women's Hospital and Harvard Medical School, Boston.

Using the Medicare, QuintilesIMS PharMetrics Plus, and Truven Health MarketScan databases, the researchers identified adults with RA who had newly started tocilizumab or a TNFi after failing a different TNFi, abatacept, or tofacitinib.

The investigators compared 10,393 adult patients with RA who had newly started tocilizumab with a set of 26,357 TNFi initiators who were



Dr. Kim

propensity-score matched to the tocilizumab patients on a variable 1:3 ratio to simultaneously account for the confounding often inherent in observational studies. In this case, the investigators tried to account for potential baseline confounders that are thought to be potentially related to RA severity or duration or the development of malignancy, such as comorbid conditions; the prior use of disease-modifying antirheumatic

drugs, NSAIDs, steroids, opioids, and other prescription drugs; and markers of health care utilization intensity, such as cancer screening tests.

Results showed that the risk of incident malignancy – excluding nonmelanoma skin cancer – was similar between the two groups across all three databases with a combined hazard ratio of 0.92 (95% confidence interval, 0.74-1.14) in tocilizumab users, compared with TNFi users. Incident malignancy was defined as having two diagnosis codes within 2 months.

Secondary analyses conducted by cancer subtype and all-cause mortality showed similar results.

According to Dr. Kim, the findings are particularly relevant because the study involved patients with active RA who were treated with at least one other biologic or tofacitinib.

"In other words, even among RA patients who were exposed to more than one biologic, the risk of cancer was similar between tocilizumab and TNF inhibitor initiators," she said in an interview.

Dr. Kim conceded that a lack of data on patients' disease duration or activity limits the conclusions

that can be drawn from the study.

However, she said that, since the two active treatments were compared for the same indication – active RA in patients who failed at least one other biologic agent or tofacitinib before – the "baseline confounding by disease severity/activity is expected to be less than when comparing tocilizumab versus methotrexate" on an untreated patient.

Dr. Kim noted that, as is true in drug safety studies, long-term data are always important. "Since tocilizumab was first introduced in the United States approximately 8 years ago, we anticipate to have more long-term safety data in near future," she said.

Dr. Kim and several other authors reported receiving grant/research support from Genentech/Roche and other companies. Three authors are employees of Genentech, which markets tocilizumab.

CLINICAL SCIENCE SESSION

Cancer and inflammation

Wednesday 14:15 – 15:45

Auditorium / Balcony

Severe structural osteoarthritis sparks depressive symptoms

The severity of knee osteoarthritis has a significant impact on the rate of onset of depressive symptoms, based on data from more than 1,000 patients in the Osteoarthritis Initiative that will be presented today.

The new research adds OA structural severity as a contributing risk factor for the onset of depressive symptoms and confirms previous studies' findings about rising depression-onset rates with greater pain and physical dysfunction.

"Studies have consistently shown that depressive symptoms are associated with worse osteoarthritis (OA) disease severity, both cross-sectionally and longitudinally; however, there is a lack of research focused on identifying the specific components of OA (as a disease and illness) that contribute to the onset of depressive symptoms in nondepressed OA patients," first author Alan Rathbun, PhD, MPH, of the departments of epidemiology and public health and medicine at the University of Maryland, Baltimore County, USA, said in an interview.

"There are no standardised medical management strategies that are effective and have been widely adopted in routine clinical practice for OA patients who have comorbid depressive disorder. The most recent clinical care guidelines for OA patients advise treating depression, but if OA disease severity contributes to the development and worsening of depressive symptoms, it may be necessary to intervene on both conditions simultaneously in order to successfully manage them," he said.

The study comprised 1,652 individuals with radiographic knee OA who were involved in the Osteoarthritis Initiative. The patients had radiographic disease of Kellgren-Lawrence grade 2, 3, or 4.

The onset of depressive symptoms was evaluated at baseline and at three follow-up visits among nondepressed participants using the Center for Epidemiological Studies Depression (CES-D) scale and its corresponding screening threshold of 16 or higher.

Disease severity in the highest



Dr. Rathbun

quintiles as measured by three factors – 20-meter gait speed, minimum joint space width, and WOMAC pain subscale – was significantly associated with risk of depressive symptom onset. The odds ratios for onset of depressive symptoms comparing the highest to lowest quintiles of disease severity were 1.80 for gait speed, 2.10 for joint space width, and 2.21 for pain; all were statistically significant.

The findings remained significant after the researchers controlled for potential confounders including demographics, lifestyle factors, socioeconomic status, Charlson comorbidity index, K-L grade, and WOMAC functional disability and joint stiffness, as well as CES-D score, body mass index, analgesic use, and knee injuries.

"Indeed, the findings were surprising, specifically, because results showed that all three components of OA disease progression were associated with an increased risk for the onset of depressive symptoms in those with radiographic knee OA," Dr. Rathbun said. "Prior research has demonstrated associations between pain severity and depressive symptoms as well as physical function and depressive symptoms in OA patients. However, our findings imply that worsening structural disease severity (as measured by joint space width) is also associated with an increased risk for developing depressive symptoms," he said.

"The clinical implications of

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Postmarketing surveillance, shared decision making lie atop biosimilar concerns Continued from page 1

Agency as well as convincing equivalence data between approved bsDMARDs and their comparative originator agents.

However, Prof. Kvien noted that switching from an originator bDMARD to a bsDMARD remains a more controversial issue, particularly from the patients' point of view.

"Imagine that you have a rheumatic disease – and you have been treated successfully with a bDMARD for many years. The doctor tells you that we now have a less expensive alternative – it is not identical to your drug but very similar. ... Both patients and doctors may of course raise concerns," Prof. Kvien said.

"Imagine that you have a rheumatic disease – and you have been treated successfully with a bDMARD for many years. The doctor tells you that we now have a less expensive alternative – it is not identical to your drug but very similar. ... Both patients and doctors may of course raise concerns."

Nevertheless, the available evidence does support the safety of switching between agents, particularly evidence from the randomised, controlled NOR-SWITCH study involving patients who had used the originator infliximab brand Remicade for an average of 6-7 years.

The Norwegian government-

sponsored trial showed that switching from the originator to its biosimilar CT-P13 was not inferior to continuous treatment with the originator.

Prof. Kvien, who was the principal investigator of the NOR-SWITCH study, said the results were consistent across the study's primary endpoint of disease worsening as well as secondary endpoints, including disease activity, patient-reported outcome measures, biomarkers, adverse events, and trough drug levels, as well as anti-drug antibody formation.

However, he points out that NOR-SWITCH covered switching with one agent, and there is still a need for more solid data on switching between other bDMARDs and bsDMARDs.

"Ideally, some additional switch studies should be performed for other biologicals, for example from originator adalimumab to biosimilar adalimumab," he said.

However, he noted that switching has been associated with a placebo effect and studies would therefore need to be blinded – a difficult thing to achieve when the drugs were administered by patients.

As it probably isn't in the interests of any company to sponsor a NOR-SWITCH-like study for originator bDMARDs, Prof. Kvien said it may be down to individual governments and health systems to conduct these trials.

"The investment of the Norwegian government in the NOR-SWITCH study has definitely been paid back by a nearly 100% transition of patients from the originator to the much less expensive biosimilar infliximab," he notes.

Keeping the patient at the centre of the decision

At the same session, PARE Vice



Prof. Kvien



Mr. Wiek



Ms. French

a shared decision between patient and doctor, and the patient must agree to both the biosimilar drug and the pharmaceutical dosage form.

It's a sentiment that Tracy French, a registered nurse at University Hospitals Bristol (UK), will

echo in her presentation.

She said that allowing patients to be a part of the decision-making process is vital to maintaining patient-clinician trust that has often been built up over many years.

According to the United Kingdom's clinical body, the National Institute of Clinical Excellence (NICE), the shared decision-making process involves a scenario where care or treatment decisions are fully explored along with their benefits and risks; the different choices available to the patient are discussed; and a decision is reached together with a health and social care professional.

Ms. French stresses that to make the switch with true shared decision making it is vital that service provision is made ahead of the switching process, including extra funding for more staff support if this is needed.

"This enables a one-to-one consultation, so switching is quick to make maximum cost savings but keeps the patient at the centre of the whole process," she said.

Prof. Kvien reported serving as a consultant to many companies developing biosimilars. Mr. Wiek and Ms. French had no relevant disclosures.

President of Germany, Dieter Wiek, will talk to delegates about whether the EULAR's member organisations of PARE have changed their view on the use of biosimilars in light of new evidence and data.

According to Mr. Wiek, although the results of some studies, such as NOR-SWITCH, have alleviated concerns around switching patients from originator biologics, the general view is that patients want to have more studies after market approval by the European Medicines Agency.

He said it is also really important to have a solid pharmacovigilance process in place in the form of patient registries.

"Registries for all biologicals should be a must. To my mind, it is not acceptable that we spend thousands of euros annually on a drug for a patient, but we do not collect data to track side-effects, comorbidities. ... Being able to track the drugs the patient takes should be mandatory," he said.

It is also crucial that patients are part of the decision-making process when deciding whether to make a switch in therapy from an originator to a biosimilar.

Yet this is something that doesn't happen in all countries, said Mr. Wiek, who is a past Chair of the Standing Committee for PARE.

It is the view of PARE that no patient should be switched from an original product to a biosimilar because of cost-effectiveness against their wish, Mr. Wiek said. Also, a switch should always be based on

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our findings are that the onset of depressive symptoms in OA patients is related to worsening pain, physical function, and structural disease severity," Dr. Rathbun explained. "Given that OA disease severity significantly contributes to depressive symptoms in this population, it is necessary to address both the sequelae (depression)

and the primary condition (OA) in order to successfully alleviate their combined symptomatic burden," he noted.

"Future studies need to ascertain whether depressive symptoms modify clinical response to analgesic medications in OA patients," said Dr. Rathbun. "Considering that analgesics are often the first-line treatment for OA

patients and the high prevalence of depressive symptoms in this population, comorbid depressive disorder may be an important contributor to ineffective medical management in the many OA patients who undergo total joint replacement," he said.

Dr. Rathbun disclosed research support from the Rheumatology Research Foundation, and the study

was supported by the Rheumatology Research Foundation's Scientist Development Award.

FROM BENCH TO BEDSIDE

Psychological distress and pain; not all in the mind

Wednesday 14:15 – 15:45

Elicium 2

JOINT SESSION HPR / PARE

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

Wednesday 16:15 – 17:45

Amtrium