Welcome to the 2013 Congress And to Madrid, the Heart of Spain

Dear Colleagues:

I am pleased to welcome you to the 14th annual European Congress of Rheumatology. The annual EULAR congresses are now a major event in the calendar of world rheumatology. As have previous congresses during the last decade, Madrid 2013 will provide a unique event for the exchange of scientific and clinical information for the 14,000 physicians, health professionals, scientific researchers, patient group members, and industry representatives who are expected to attend this year.

EULAR congresses have grown rapidly in terms of the numbers participating and the quality of contributions. This partly reflects the increased interest in arthritis and related musculoskeletal diseases that is seen in most societies. This expansion also reflects the increased availability of information on the impact and burden of these diseases and the significantly improved potential for diagnosis and treatment. The integration of health professional and patient organisations within EULAR has proved to be a considerable stimulus for these advances.

Chronic, Long-Term Management Needed for Gout

Acute inflammatory episodes of gout should be viewed as the tip of an iceberg of chronicity and comorbidities and treated as such, according to Dr. Michael Pillinger, who will present his arguments this afternoon.

“In some ways, gout should actually be considered as two (if not more) diseases; the first is the metabolic disease of hyperuricemia, which is a metabolic disease that results mainly from either genetically based overproduction of uric acid, heritable or acquired impairment of renal insufficiency, or both,” said Dr. Pillinger, associate professor of medicine and biochemistry and molecular pharmacology at the New York University (NYU) School of Medicine.

The second disease component of gout is the inflammation resulting from the formation of urate crystals. However, Dr. Pillinger suggested in an interview before the Congress that rather than being solely an acute condition, some patients demonstrate chronic gout.

Citing Social Costs Key to Winning Funding for MSDs

When it comes to public funding for research and prevention programs, it’s usually conditions like cancer and heart disease that come out on top. But musculoskeletal conditions, which are both chronic and costly, tend to be overlooked by policymakers.

The problem is that these are diseases that patients live with, not die from, said Jacob Holch, a consultant with the Danish Rheumatism Association based in Gentofte, Denmark.

“To most people, including politicians, musculoskeletal diseases can carry hefty societal costs due to the large volume of people affected by these often disabling conditions. For instance, in Denmark osteoarthritis affects nearly 20% of adults. Another 14% report some form of back pain. Those prevalence rates translate into many early retirements and lost productivity. MSDs continued on page 8

Mr. Holch said, “One politician with whom I attended a meeting actually said, ‘Everybody has a sore back. I have a sore back.’”

Mr. Holch and his colleagues at the Danish Rheumatism Association are hoping to turn this trend around by showing policymakers that musculoskeletal diseases can carry hefty societal costs due to the large volume of people affected by these often disabling conditions. For instance, in Denmark osteoarthritis affects nearly 20% of adults. Another 14% report some form of back pain. Those prevalence rates translate into many early retirements and lost productivity.

MSDs continued on page 8
Letter From the EULAR Secretariat

Dear Congress Participants:

It is with great pleasure that we welcome you to the EULAR Congress Madrid. We take this opportunity to thank all of you who are showing an interest in what EULAR does and offers, and especially all those actively taking part in and supporting the myriad EULAR activities. We are grateful and happy to see so many familiar faces in Madrid as well as numerous new ones.

We are living in a period of continuous change and unrest in many areas. In this environment, we have been trying to keep the EULAR Congress a steady place, where there is a unique ambiance for learning but also for meeting and networking with colleagues from around the world. For some 14,000 physicians, health professionals, scientific researchers, patient group members, and industry representatives, this makes up a good and joyful part of their Congress experience. In addition to all the learning that is awaiting you at EULAR 2013, we have made great efforts to offer ample space, indoors and outside, for meeting with colleagues and chatting or having a serious scientific discussion.

Our Scientific Committee and all those working behind the scenes have again developed an exceptional Congress. The EULAR 2013 scientific programme provides countless opportunities to hear about the latest advances and cutting-edge research in rheumatology through lectures, workshops, abstracts, and poster presentations. The poster areas are accessible from early morning, and a fair selection of Poster Tours are offered during poster sessions. Our 350 invited speakers highlight clinical innovations, clinical practice, and basic or translational research and help put the new science into perspective. And as a novelty at EULAR 2013, learning will not stay at the back home.

A new EULAR strategy, labelled “Vision 2020,” was finalised toward the end of 2012. Many EULAR individuals and member societies have given their views and advice to make it ambitious while tangible. Seven main strategic objectives serve EULAR as a highway toward the future, on which we will no doubt encounter challenging tasks, from coping with new regulations, to responding to the changing needs of rheumatologists, health professionals, and patients, to finding answers to a continuously globalising world. One innovation already in place deserves special mention: The establishment of the European Rheumatology Research Foundation (ERRF) has been a major creative effort for EULAR over the past 18 months. Read more about ERRF in tomorrow’s issue of the EULAR Congress News.

Strategic planning has not stood in the way of the practical work that remains at the heart of EULAR. Among other things, we have developed new recommendations on the management of specific diseases, and we have provided research grants to individual investigators in Europe. For instance, we have organised and delivered educational courses for rheumatologists, both young and experienced. We have facilitated attendance at EULAR courses and the EULAR Congress with bursaries for those in need. Finally, we have recognised individuals for special achievements in rheumatology. Don’t miss the Opening Ceremony this evening which will feature award winners presented by the EULAR President.

Over the past 12 months, new EULAR Recommendations have been published on:
- Management of adult and paediatric lupus nephritis (devised in collaboration with the European Renal Association).
- Use of imaging of the joints in the clinical management of RA.
- EULAR’s definition of erosive disease, made necessary by the 2010 ACR/EULAR RA classification criteria.

More are currently under review by the editors of the EULAR Journal. While publishing recommendations is one thing, making people aware of them, and even applying them on a broader scale, is quite another. Improving dissemination is therefore an issue that the EULAR Executive Committee has just recently attended to by approving a project seeking to develop and implement a guiding practice.

In the EULAR educational arena, e-learning continues its way up on our popularity scale as more and more (young) rheumatologists are subscribing to our courses. In September 2012, the new introductory oline course on ultrasound got off to a vibrant start with some 300 registered participants. Those of you who are fans of our traditional Postgraduate Course may be happy to hear that it will again be offered this year, with a revised and slightly shorter programme, on 18-21 November in Prague, Czech Republic. For those more inclined to reading, note that the 2012 edition of the affordable EULAR Textbook on Rheumatology remains available. In fact, more than 1,000 people have bought this book in the past year. More copies are on sale at the BMJ booth in the EULAR Village. Take a look at the education brochure inserted in your Congress bag, which provides a good overview of what’s available from EULAR.

Our EU Public Affairs Group has had another year of relentless effort and activity in the European political arena in Brussels. Its main focus was on the research framework programme “Horizon 2020,” which defines the EU’s focus on research in the next 7 years. Our efforts at bringing rheumatic and musculoskeletal diseases to a higher and more explicit level of attention by the politicians seem to be showing an effect. Both the EU Council and the Parliament have taken on board EULAR demands for RMDs in the Horizon 2020 main documents. And for good reason: RMDs are among the most prevalent, disabling, and costly chronic conditions in Europe, affecting more than 120 million people of all ages.

Networking has always been a key aspect of the EULAR Congress. The opportunities are many and all around. Let me just remind you of the official Opening Ceremony this evening as well as the Congress Dinner on Friday, which will take place at the Palacio del Negralejo on the outskirts of Madrid and promises to be a memorable international event with truly Spanish flavour.

EULAR now wishes you a successful Congress experience, many new insights, and a great time with old and new friends in a wonderful city.

Heinz Marchesi
Executive Director
EULAR Secretariat

Congress Dinner at the Palacio del Negralejo

Friday, 14 June, 20:30 – 24:00
Price: EUR 95 per person (not included in the registration fee)

The Congress Dinner is a great opportunity to see and experience an historic building while enjoying a relaxed evening with dinner among colleagues from around the world. In 1790, on the ruins of the “Negrales” castle, a family from Madrid’s nobility built their country palace. Later, well into the 19th century, the Marquis of Villamejor founded his famous stables, home to the renowned “Figueroa” stud. In 1982 the owners decided to turn this fabulous complex into a venue for events and functions, keeping the original style but introducing all the modern functionality required for events. Such was the determination and perfectionism put into the restoration that Palacio del Negralejo can today be considered an ethnological museum where one can find countless antique farm implements, household, and decorative items. Join us this evening and taste the Spanish flavour of the place!
Treating early for long-term success: The PRIZE in RA

Wednesday 12th June, 13:00–14:30
Hall 7
Chair: Tore Kvien

Treatment targets in rheumatoid arthritis

Thursday 13th June, 08:15–09:45
Plenary Hall 6
Chair: Juan Gómez-Reino

The mosaic of RA: Assembling the pieces for optimal treatment outcomes

Thursday 13th June, 17:30–19:00
Hall 8
Chair: Bernard Combe
Meet the 2013 EULAR Abstract Award Winners!

At tonight’s Opening Plenary Session, EULAR will honour 12 researchers for their outstanding abstracts. Each winner will receive 1,000 euros.

Francesco Ciccia, M.D., is a member of the Department of Internal Medicine, Section of Experimental Rheumatology at the University of Palermo (Italy). Tonight he will received an award for his basic science research on the immunological mechanisms underlying the increased IL-23 expression in the gut of patients with ankylosing spondylitis.

B. J. E. de Lange-Broekaar, M.D., of the Department of Rheumatology at Leiden University Medical Centre in The Netherlands, is receiving an award for his clinical research in which she assessed patterns of synovitis on contrast-enhanced MRI and its relation to pain and radiographic severity.

Diederik de Rooy, M.D., LL.M, of the Department of Rheumatology at the Leiden University Medical Centre in The Netherlands, will be honoured tonight with an award for his basic science research in which he identified a genetic variant in the region of MMP-9 that is associated with serum levels and progression of joint damage in rheumatoid arthritis.

Andrew P. Diamantopoulos, M.D., Ph.D., is a postdoctoral fellow at Medical Faculty, Norwegian University of Science and Technology (NTNU) in Trondheim, Norway. He will be receiving an award for his clinical science research that took the form of a retrospective study designed to examine whether the implementation of the “fast track” principle in an outpatient clinic for GCA patients could reduce the rate of transient and permanent visual loss.

B. I. E. de Lange-Broekaar

Bruno Fautrel, M.D., Ph.D., Professor of Rheumatology at Pierre & Marie Curie University in Paris, is being honoured tonight for his clinical science research in a randomized controlled trial on the impact of progressive spacing of TNF-blocker injections on signs and symptoms of rheumatoid arthritis patients in DAS28 remission.

Uta Kiltz, M.D., who is on the faculty of the Rheumatology Department at the Rheumazentrum Ruhrgebiet in Herne, Germany, is receiving an award for her clinical science research concerning the fifth and final phase of development of a health index in patients with ankylosing spondylitis (ASAS HI). Dr. Kiltz won this clinical science abstract award in 2012 as well for earlier work on this measure.

Masahiro Kondo, MSPHR, is a member of the First Department of Internal Medicine at University of Occupational and Environmental Health, Kitakyushu, Japan. He will receive a basic science abstract award for his work on the inhibitory effects of IL-17 on chondrogenic differentiation of human mesenchymal stem cells (MSC) through the phosphorylation of SOX9. Inactivation of IL-17 RA joints should be important for the clinical settings.

Andreas P. Diamantopoulos, M.D., Ph.D., is on the faculty of the Department of Experimental Medicine and Rheumatology at the Queen Mary University of London. Tonight he will be receiving a basic science abstract award for his work investigating IL-21 mRNA expression in Sjögren’s syndrome (SS) salivary glands involvement, to correlate expression with markers of inflammation such as CXCL13, Ltb, BAFF, as well as markers of B cell differentiation AID, Pax5 and Blimp1, and then to assess the relationship of IL-21 and Tfh cells with the development of functional ectopic germinal centers.

Andrew Leask, Ph.D., is professor of dentistry at the University of Western Ontario in London, Canada. Tonight he will be receiving a basic science abstract award for his work on whether in a murine model of scleroderma: (a) loss of PTEN (a phosphatase that suppresses adhesive signaling) expression in fibroblasts also results in lung fibrosis and (b) whether CCN2 mediates lung fibrosis caused by loss of PTEN.

William Murray-Brown, M.D., is on the faculty of the Department of Experimental Medicine and Rheumatology at the Queen Mary University of London. Tonight he will be receiving a basic science abstract award for his work investigating IL-21 mRNA expression in Sjögren’s syndrome (SS) salivary glands involvement, to correlate expression with markers of inflammation such as CXCL13, Ltb, BAFF, as well as markers of B cell differentiation AID, Pax5 and Blimp1, and then to assess the relationship of IL-21 and Tfh cells with the development of functional ectopic germinal centers.

Frank W. Roemer, M.D., is Section Chief Musculoskeletal Research in the Department of Radiology at the University of Erlangen-Nuremberg, Erlangen, Germany, as well as Co-Director of the Quantitative Imaging Centre at Boston University School of Medicine, Boston, U.S.A. His academic rank at both universities is Associate Professor. He will receive an award for his clinical science research finding that subchondral bone marrow lesions predict incident radiographic osteoarthritis. This finding comes from his study of 110 knees that developed radiographic knee OA between a baseline exam and final follow-up 4 years later.

Benjamin Terrier, M.D., Ph.D., is a member of the Internal Medicine Department at the Cochin Hospital in Paris. He will receive an award tonight for his basic science research in which he used flow cytometry to measure the expression of FCR1 and decreased expression of FCR1 on clonal CD21+/lo marginal zone-like B cells compared to other B cell subsets from the HCV patients and healthy donors. They produced two anti-FCRL5 recombinant immunotoxins (F56-IT and F25-IT) that showed specific cytotoxicity against FCRL5-expressing clonal CD21+/lo marginal zone-like B cells isolated from HCV patients as well as FCRL5-transfected cell lines. Taken together, the findings suggest that FCRL5-targeting therapies could be a specific treatment of HCV-related lymphoproliferation and other FCRL5-positive malignancies and/or autoimmune B-cell disorders.

Julien Wipff, M.D., Ph.D., is on the faculty of the Rheumatology A Department at University Paris (France) Descartes. Dr. Wipff is being recognized for his clinical science research undertaken to describe precise clinical, biological, radiological, and histological features of chronic recurrent multifocal osteitis (CRMO) in the absence of validated international diagnostic criteria. With his fellow investigators, Dr. Wipff evaluated 164 patients with at least one episode of CRMO. Findings suggest that clinical evolution and repeated bone scans and MRIs could confirm the multifocal pattern of osteitis in initial unifocal form. Up to 12% of bone biopsies could be avoided by calculating the Jansson scores. NSAIDs remained the most effective first-line treatment. Men and patients with multifocal disease at presentation were most likely to need bisphosphonates and/or anti-TNF alpha.
Roche-sponsored satellite symposia at EULAR 2013

Tailoring choice of therapy to meet patients’ needs:

What are the differences between available treatment options in RA?

Friday 14 June 2013, 08:15–09:45, Hall 8, IFEMA Madrid

This educational programme features an eminent panel of rheumatology experts, who will be sharing insights and data behind the key considerations underlying treatment choice in current clinical practice – with a view to both meeting individual patients’ needs and optimising outcomes in RA

**Chair:** Maxime Dougados, France

**Evolving choices in RA treatment: What are the important differences between the mechanisms of action?**

Ernest Choy, UK

**Translating the evidence into clinical context: What are the considerations for tailoring treatments to optimise outcomes in RA?**

Paul Emery, UK

**Insights into the safety profiles of RA treatments: What does the long-term evidence tell us?**

Andrea Rubbert-Roth, Germany

**Summary**

Maxime Dougados, France

**Question and answer session**

*This presentation is not intended for physicians practicing in the USA*

Different needs, different options:

Clinical challenges and considerations in tailoring RA treatments to patients

Friday 14 June 2013, 17:30–19:00, N101 + N102, IFEMA Madrid

**Chair/Moderator:** John Isaacs, UK

**Panel**

Maya Buch, UK

Andrew Östör, UK

Cem Gabay, Switzerland

Please join us for an interactive panel discussion featuring the latest clinical trial and registry data, real-time audience opinion polls and live audience Q&A. Our distinguished faculty will be discussing their clinical insights and experience on topics that include:

- The growing range of treatment options in RA
- The importance of considering patient factors in therapeutic decision-making
- Medication non-adherence in RA, including data on prevalence and clinical impact

*This presentation is not intended for physicians practicing in the USA*
2013 Health Professional Abstract Awards

This year EULAR is continuing to honour excellence in research by offering the Health Professional Abstract Awards. This year’s three winners each will receive an award of 1,000 euros in recognition of their outstanding research abstracts in their field. EULAR President Maxime Dougados will present these awards tonight during the Opening Plenary Session.

Marcelo Souza, a doctoral student in the Rheumatology Division of Universidade Federal de Sao Paulo (Brazil), is a physiotherapist. His winning research assessed the benefits of progressive muscle strengthening using a Swiss ball in patients with ankylosing spondylitis.

Mr. Souza and his associates randomized 60 patients with AS to either a regimen of twice-a-week exercise with a Swiss ball for 16 week or control activity. The Swiss ball weight was reassessed and increased every 4 weeks as appropriate. At the end of the assessment, the investigators found that the progressive muscle strengthening using a Swiss ball was effective in improving muscle strength and walking performance in patients with AS. The exercise program showed good tolerance, as assessed by patient satisfaction, without deleterious effects on disease activity.

Emma K. Stanmore, Ph.D., M.Res., B.Nurs. (Hons), D.N., R.N., is a Lecturer in Nursing at the University of Manchester (England). She is receiving the award for her prospective study on falls, fear of falling, and risk factors in adults with rheumatoid arthritis. The investigators recruited 535 participants, who were followed for 1 year, during which time they had a total of 598 falls. Findings from multivariate logistic regression analysis showed that when taken in combination with other factors, a history of multiple falls in the previous one year was the most significant predictive risk factor. The most significant modifiable risk factors were swollen and tender lower limb joints (hip, knee, and ankle), use of psychotropic medication, and increasing fatigue. Adults of all ages with RA are at high risk of falls and fall-related injuries. RA patients’ risk of falling can be identified by asking whether patients have fallen in the past year. Management of swollen and tender lower limb joints, avoiding fatigue, and consideration of psychotropic medicines may be the most effective strategy to reduce falls in this group of patients. Fear of falling, pain, weak lower limb strength and poor balance are other useful clinical indicators that may be modified to prevent falls.

Martijn Oude Voshaar, a doctoral student at University of Twente in The Netherlands, assessed predictors of no improvement in subjective health perception in newly diagnosed RA patients with a good DAS28 response at 12 months in the DREAM (Dutch Rheumatoid Arthritis Monitoring) tight control cohort. Mr. Voshaar and his associates identified the 162 (57%) out of 282 patients in the cohort who achieved a good DAS28 by the end of 12 months of tight control. Of these, 40 (24.7%) did not consider their health to have improved since starting treatment (non-improvers). The majority of patients with a good DAS28 response after 1 year of tight control treatment considered their health to have improved. However, a substantial minority did not consider their health to have improved, despite significant clinical improvements in disease activity. These results suggest that clinical improvements did not necessarily equate to improved subjective health. One possible explanation is that pain and fatigue are patient-reported outcomes that may not be adequately represented in current clinical outcome measures in RA research.

Undergraduate Abstract Award Winners

In a new honour, three medical students are slated to receive abstract awards from EULAR for their clinical science research in rheumatology. Each will receive a prize of 1,000 euro and will be honoured tonight by EULAR President Maxime Dougados. These sterling examples of the newest generation of medical intellects are:

Christien Rondaan, a medical student at the Groningen University Medical Centre in The Netherlands. Her research, which will be presented as a poster (abstract 0306) on Thursday, investigated whether patients with autoimmune disease are likely to mount less than robust cellular and/or humoral responses to the varicella zoster vaccine (VZV). Ms. Rondaan and her associates studied VZV-specific immunity in 78 patients with systemic lupus erythematosus, 71 patients with granulomatosis with polyangiitis (GPA), and 65 age- and sex-matched healthy controls. Results of ELISA testing showed that patients with SLE have increased antibody levels against VZV compared to levels detected in controls. This finding cannot be explained by polyclonal hypergammaglobulinemia given that antibodies to diphtheria among the SLE patients were decreased in comparison to controls. However, cellular immunity was decreased in these patients as well as in GPA patients. The increased prevalence of VZV in SLE and GPA patients is due to a poor cellular response to VZV. Vaccination strategies should not be based upon humoral immunity and should aim to boost cellular immunity against VZV.

Lisa Theander, a medical student at Sahlgrenska Academy at the University of Gothenburg, plans to graduate from medical school in January 2014. She will present her award-winning research in a poster (abstract 0159) on Friday. Along with her associates, Ms. Theander examined whether treatment with TNF-inhibitors has any effect on the risk of developing severe Extra-articular rheumatoid arthritis (ExRA). In addition, her research was designed to determine whether baseline data obtained by questionnaire could be used to develop potential predictors of ExRA. She found that TNF-inhibitors did not have any major effect on the incidence of severe ExRA in this sample. The best predictors of ExRA were male gender, long duration of disease, and greater disability as measured by HAQ.

Anne-Priscille Trouvin will graduate in 2013 from the Rouen University and will continue her training as a rheumatologist there, with a second specialisation in chronic pain in rheumatoid diseases. Ms. Trouvin will present her award-winning research at a poster (abstract 0215) on Friday. Her research was designed to assess the usefulness of periodical B-cell analysis to determine whether it predicts clinical relapse of rheumatoid arthritis in patients treated with rituximab. In the prospective single-centre observational study of 39 patients with RA treated with rituximab 1g twice 15 days apart, patients were monitored clinically and biologically every 2 months until retreatment. The assessment showed that the presence of transitional and memory B cell predicted a relapse in the 4 months that followed repopulation.
Manage Between Episodes

Gout from page 1

Inflammation in between attacks, even if they are feeling well.

“Advanced imaging supports that many people with only intermittent attacks of gout actually have occult deposits of urate crystals within their tissues, and there is some evidence that this may result in chronic, low-level inflammation that may potentially have adverse consequences, including for comorbidities.”

Comorbidities such as diabetes, obesity, hypertension, cardiovascular disease, renal disease, and hyperlipidemia are common among patients with gout, and the majority of patients demonstrate more than one of these.

“All of these comorbidities make gout management harder, since gout therapies not infrequently may exacerbate one or more of these comorbidities, a fact physicians do not adequately take into account,” said Dr. Pillinger, who is also director of the Crystal Diseases Study Group in the NYU division of rheumatology.

Approaching and treating gout as a chronic condition rather than as an acute disease means not simply controlling the inflammation but addressing the root cause of the disease.

“That strategy will neither affect urate levels nor fully address the consequence of urate deposition, including bony destruction around tophi,” Dr. Pillinger said. “To get to the root of the problem, we need to address the serum urate level using both lifestyle changes and pharmacotherapy, and when this is done successfully and persistently, there is ultimately no reason why any well-controlled patient should ever suffer a gout attack.”

He advocates a greater effort to control urate levels earlier in the disease course, before tissue deposits of urate build up, as these can make it much harder to treat the disease later on.

“These deposits have adverse effects, whether recognised, such as clinical tophi, or occult; they take up space, can distend tissues and cause pain, damage tissues and bones, may ulcerate and/or become infected, and are a marker of worse gout and poorer quality of life,” he said.

While current guidelines recommend this approach, Dr. Pillinger said part of the problem is the perception of gout as an occasional disease that does not need to be managed in between episodes.

You are invited to attend the educational symposium

NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

Values and controversies

Wednesday 12th June 2013 | 13:00–14:30
Room N105+N106, North Convention and Congress Center, Feria de Madrid, Spain

Programme
Chair: Robert Landewé, the Netherlands

13:00–13:10 Welcome and introduction
Robert Landewé, the Netherlands

13:10–13:30 Non-radiographic axSpA: clinical diagnosis or classification?
Martin Rudwaleit, Germany

13:30–13:50 Value and dangers of magnetic resonance imaging in non-radiographic axSpA
Walter Maksmysnych, Canada

13:50–14:10 Why is non-radiographic axSpA different from fibromyalgia?
 Filip van den Bosch, Belgium

14:10–14:30 Question and answer session
All faculty

The ‘Non-radiographic Axial Spondyloarthritis: Values and Controversies’ symposium is designated for a maximum of (or ‘for up to’) 2 hours of European external CME credits. Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity.

This event has been funded by an unrestricted educational grant from UCB

Long-term management of gout must address the root cause of the disease.
Sessions to Be Recorded

Madrid from page 1

This year’s Congress will also continue our initiative of closer cooperation with primary care physicians and professionals – a commitment we started in London in 2011. The Primary Care track received more and better abstracts than in the two previous years.

The EULAR Congress 2013 in Madrid will once again offer a wide range of topics including clinical innovations and clinical translational and basic science.

In addition, there will be meetings organised by people with arthritis, health professionals, and the health care industry.

Of the almost 4,000 abstracts that were received, 86% focus on clinical medicine. The majority are from Europe, but most of the major continents on the globe are represented.

RA Comorbidity Management

BY TARA MAELE

A few major components are key to reducing the impact of comorbidities in patients with rheumatoid arthritis, according to Dr. Johan Askling of the Karolinska Institutet in Stockholm. Dr. Askling will be discussing each of those eight areas in his presentation this afternoon.

“The talk will discuss some of the prime comorbidities in RA, what they are, what their main drivers are, how they may be identified and intervened against, and also some suggestions for how to implement this thinking into an otherwise busy outpatient clinic,” Dr. Askling said in an interview before his presentation.

He noted that effectively managing RA while keeping in mind likely comorbidities can influence for the better every aspect of a patient’s treatment.

“Prevention and treatment of comorbidities are increasingly recognized as a key to reduced disease burden, improved quality of life, and improved safety of antirheumatic treatments,” Dr. Askling said. In fact, management of RA is not dissimilar to management of other chronic conditions vulnerable to comorbidities.

The situation is similar to that of diabetes care. Normalised blood glucose is a good start, but “we all know the importance of also intervening against hypertension, albuminuria, etc., in order to prevent the long-term comorbidities of diabetes,” he said.

The first step to effective management is knowing what major comorbidities occur with rheumatic disease. Those with RA are at higher risk for cardiovascular disease, for example. Among the comorbidities that Dr. Askling will be discussing this afternoon are cardiovascular diseases, osteoporosis, and certain infections that are typical in RA.

One must know what those comorbid conditions look like and how they typically present. A key part of Dr. Askling’s talk will involve discussion of whether those comorbidities occur because of RA or the interventions used to treat the RA, or for other reasons entirely.

In rheumatology, “chronic inflammatory joint diseases are associated with significant comorbidities, either through uncontrolled disease or through our antirheumatic therapies,” he said. “So, besides reducing joint inflammation, we need to keep an eye on a series of other conditions, the importance of which – in the long run – may outweigh that of the arthritis per se.”

Once clinicians understand what the possible comorbidities are, their symptoms, and how they manifest, successful management then requires risk assessment and management, thus paving the way for preventive care including educating the patient on any lifestyle interventions that may prevent these conditions, such as increasing physical activity or improving diet to reduce cardiovascular risks.

Cost Efficiency a Concern

MSDs from page 1

Mr. Holch will detail two analyses carried out by his organisation in his presentation this afternoon.

In the first study, they examined the social costs of back pain, including the direct treatment costs, lost productivity, and government expenses for benefits.

The study, which relied on public survey data and registry data, found that the annual price tag for back pain was nearly 2.2 billion euros.

The second study was a cost-benefit analysis for public investments in improved rehabilitation programs. In Denmark, the government spends about 480 million euros annually on “sickness benefits” for individuals with musculoskeletal diseases. Early retirements because of these conditions cost Danish society an additional 1 billion euros each year.

The study examined the impact of four different models of rehabilitation that have been developed and tested for patients with musculoskeletal diseases. The analysis showed that by implementing these evidence-based, interdisciplinary programs at the local level, state and local governments could save about 160 million euros each year.

These figures are exactly the type of ammunition that advocates need to make their case to politicians during a time of global belt-tightening, Mr. Holch said.

“In most European countries, the interest in cost-efficiency measures within the health sector has increased dramatically during the economic crisis, which further stresses the need for a comprehensive view on disease prevention and treatment,” he said.

While in most cases it is patient advocacy groups that lobby politicians for funding, Mr. Holch said clinicians can play an important role.

“Clinicians always play a vital role in informing society about diseases and their consequences, as they care for affected patients firsthand,” he said. “As an advocacy organization, we depend enormously on clinicians to provide us with the latest knowledge on musculoskeletal diseases and the current state of concern, and so do politicians.”

How to Treat/Manage HOT Session 2

Wednesday 17:00 – 18:30

Hall 7
NEW SUBCUTANEOUS FORMULATION

The first and only selective T-cell co-stimulation modulator approved for the treatment of RA

Now available in both IV and SC formulations

ACHIEVE BALANCE FROM YOUR RA BIOLOGIC THERAPY

EFFICACY

SAFETY

ORENCIA

Bristol-Myers Squibb

Early. Effective. Sustained.1,2

REFERENCES
Biologics and improved strategies for their use have significantly reduced the sick leave and disability rates among patients with rheumatoid arthritis, but more-efficient, multi-professional intervention strategies are still needed to reduce the relatively high incidence of sick leave, said Mathilda Björk, Ph.D., who will present her findings this afternoon.

The Swedish Early RA (TIRA) cohort study comparing sick leave rates between two cohorts of patients with rheumatoid arthritis, 10 years apart, found the percentage of people on sick leave 2 years after inclusion was nearly halved (28%) in the 2005-2008 TIRA-2 cohort, compared with the 1996-1998 TIRA-1 cohort (54%).

The earlier TIRA-1 cohort included 320 patients – only 120 of whom were still participating at the 2-year follow-up – and the TIRA-2 cohort included 522 patients – 275 of whom were still participating in the study at 2 years – with recent-onset rheumatoid arthritis and who were under age 62.

Both cohorts received early multi-professional interventions, while patients in the more recent TIRA-2 cohort were treated more aggressively with disease-modifying anti-rheumatic drugs, mainly methotrexate, starting at their first visit, as well as biologics when required.

“During the year after diagnosis, the mean days of sickness benefit among patients in the more recent TIRA-2 cohort were treated more aggressively with disease-modifying anti-rheumatic drugs, mainly methotrexate, starting at their first visit, as well as biologics when required,” said Dr. Björk in an interview.

The researchers suggested that changes in political policies and the sickness insurance system may also have had some impact on the differences in sick leave between the two cohorts.

Despite the significant reductions in sick leave, as well in sickness and disability benefits, in the cohort treated more aggressively and with biologics, the researchers suggested that more could be done to address the persistently high rate of sick leave among individuals with rheumatoid arthritis.

“The impact of rheumatoid arthritis on an individual’s ability to work is a complex interaction of biological, psychological, social, and occupational factors,” according to Dr. Björk.

“The interventions need to have a wider perspective than the rheumatoid arthritis per se and [should be] done in a close interaction between the patient, clinicians, employers, and policymakers early in the disease process.”

The researchers declared no conflicts of interest relevant to the study.

Strategic Use of Biologics Have Reduced Sick Leave in RA, but Room for Improvement Remains

Biologic agents are changing the landscape of treatment for rheumatoid arthritis (RA). Biologics reduce disease activity and disability, but their use is limited by high cost and serious adverse events. The benefit of such therapy needs to be considered in the whole picture of the disease, including productivity and costs. To this end, an international expert panel discussed the cost-effectiveness of biologics and their role in improving quality of life, and presented preliminary data on the use of biologics for the treatment of juvenile idiopathic arthritis.

Newer treatment regimens with biologics cut days of sick leave.

The study, conducted by Dr. Björk from the School of Health Sciences at Jönköping University, Sweden, and her colleagues, also found that the newer treatment regimes significantly reduced the mean days of sickness benefit and disability.

“During the year after diagnosis, the mean days of sickness benefit among patients in the more recent TIRA-2 cohort were treated more aggressively with disease-modifying anti-rheumatic drugs, mainly methotrexate, starting at their first visit, as well as biologics when required,” said Dr. Björk in an interview.

The researchers suggested that changes in political policies and the sickness insurance system may also have had some impact on the differences in sick leave between the two cohorts.

Despite the significant reductions in sick leave, as well in sickness and disability benefits, in the cohort treated more aggressively and with biologics, the researchers suggested that more could be done to address the persistently high rate of sick leave among individuals with rheumatoid arthritis.

“The impact of rheumatoid arthritis on an individual’s ability to work is a complex interaction of biological, psychological, social, and occupational factors,” according to Dr. Björk.

“The interventions need to have a wider perspective than the rheumatoid arthritis per se and [should be] done in a close interaction between the patient, clinicians, employers, and policymakers early in the disease process.”

The researchers declared no conflicts of interest relevant to the study.

ORENCIA® (abatacept) PRESCRIBING INFORMATION

See Summary of Product Characteristics before prescribing.

PRESENTATION: 250 mg powder for concentrate for solution for IV infusion containing 250 mg abatacept per vial. Each ml contains 25 mg of abatacept, after reconstitution; 125 mg pre-filled syringe for SC injection. Each pre-filled syringe contains 125 mg of abatacept in 1 ml.

INDICATION: Rheumatoid arthritis (IV infusion and SC pre-filled syringes): Treatment of moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, in adult patients who have responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a Tumour Necrosis Factor (TNF) inhibitor. Orencia SC is indicated for treatment of moderate to severe active RA in patients who have had an insufficient response to or intolerance to or cannot tolerate TNF inhibitor therapy. Orencia SC is also indicated in combination with methotrexate for the treatment of rheumatoid arthritis when treatment with abatacept and methotrexate may be appropriate. See SmPC.

Polymyalgia Rheumatica and Juvenile Idiopathic Arthritis (pJIA) (IV infusion only): Orencia 250 mg powder for concentrate for solution for infusion is indicated for treatment of moderate to severe active polyarthritis patients 6 years of age and older who have had an insufficient response to or intolerance to or cannot tolerate TNF inhibitor therapy. See SmPC.

DOSAGE AND ADMINISTRATION: Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA. Orencia 250 mg powder for concentrate for solution for IV infusion Adults and elderly: Patients weighing ≥ 100 kg: 1000 mg (4 vials). Patients weighing ≥ 60 kg to < 100 kg: 750 mg (3 vials). Patients weighing ≤ 60 kg: 500 mg (2 vials). Orencia 125 mg solution for injection (SC administration): Adults and elderly: Patients weighing ≥ 100 kg: 750 mg (3 vials). Patients weighing ≥ 60 kg to < 100 kg: 625 mg (2.5 vials). Patients weighing ≤ 60 kg: 500 mg (2 vials). Orencia 125 mg pre-filled syringes: Adults and elderly: Treatment should be initiated with a loading dose using an intravenous infusion. Following this loading dose, the first 125 mg subcutaneous injection of Orencia should be given within 24 hours of the first IV infusion. Patients weighing ≥ 100 kg: 1000 mg (4 vials). Treatment of RA: Patients ≥ 6 to 17 years of age, weighing less than 75 kg: 10 mg/kg paediatric patients weighing 75 kg or more: to be administered adult dosage, not exceeding a maximum dose of 1,000 mg. See SmPC for details of reconstitution and administration as a 30 minute IV infusion. After initial administration, Orencia should be given at 2 and 4 weeks, then every 4 weeks thereafter.

Children: Use in children below 6 years of age is not recommended. Orencia 125 mg solution for injection (SC pre-filled syringes): Adults and elderly: Treatment should be initiated with a loading dose using an intravenous infusion. Following this loading dose, the first 125 mg subcutaneous injection of Orencia should be given within a day, then 125 mg subcutaneous injections once weekly. Patients who are unable to receive an infusion may initiate weekly injections of subcutaneous Orencia without an intravenous loading dose. Patients transitioning from Orencia IV therapy to SC administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. Children: Administration in children below 18 years of age is not recommended.

The continuation of treatment with abatacept should be reassessed if patients do not respond within 6 months.

CONTRAINDICATIONS: Hypersensitivity to the active substance or excipients. Severe and uncontrolled infections such as sepsis and opportunistic infections. Warnings and Precautions: Allergic Reactions: Caution in patients with a history of allergic reactions. Orencia should be discontinued if a patient develops serious allergic or anaphylactic reaction. Infections: Caution should be exercised when considering the use in patients with a history of frequent infections, or underlying conditions which may prompt to infection. Treatment with Orencia should not be initiated with patients with active infections until infections are controlled. Screening processes: Theoretical risk of deterioration in autoimmune disease. Immunisation: Live vaccines should not be given simultaneously or within 3 months of discontinuation of Orencia. See SmPC.

PREGNANCY AND LACTATION: Do not use in pregnancy unless clearly necessary. Women should use contraception and not breast-feed during treatment and for up to 14 weeks after last dose treatment.

UNDESIRABLE EFFECTS: In adult placebo-controlled trials the following adverse drug reactions were reported. Very Common (≥ 1/1000): upper respiratory tract infection including rhinitis, nasopharyngitis. Common (≥ 1/1000 to < 1/100): upper respiratory tract infection (including bronchitis), urininary tract infection, herpes simplex, rinitis, pneumonia, influenza, leukaemia, headache, distress, anaemia, conjunctivitis, hypertension, flushing, blood pressure increased, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatitis), alopecia, pruritus, pain in extremity, fatigue, asthma, injection site reaction, leucopenia (≥ 1/1000 to < 1/100). Rare (≥ 1/10000 to < 1/1000): Tooth infection, encephalomyelitis, herpes zoster, zoster, sarcoidosis, musculoskeletal infections, skin abscess, pyelonephritis, pelvic inflammatory disease, basal cell carcinoma, skin papilloma, thrombocytopenia, hypertension, anxiety, sleep disorder, migraine, dry eye, visual acuity reduced, vertigo, palipitations, tachycardia, bradycardia, hypertension, hot flush, vasculitis, blood pressure decreased, bronchospasm, wheezing, dyspnea, gastritis, increased tendency to bruise, dry skin, urticaria, psoriasis, arthropathy, amenaehoria, menorrhagia, infection like illness, weight decreased. Very rare (≥ 1/100000 to < 1/10000): Bacillaria, post-gastrintestinal infection, lymphoma, large neoplasms malignant, blood tightness. See SmPC for further details. LEGAL CATEGORY: POM. MARKETING AUTHORISATION NUMBER AND BASIC NHS PRICE: Orencia 250 mg concentrate for solution for infusion EU/1/07/088/001. 1 vial pack: £30.40 (Orencia 125 mg solution for injection EU/1/07/088/008, 4 pre-filled syringes with needle guard: £1209.60.
Interventions for rheumatoid arthritis may be on the cusp of shifting from treatment to prevention, given research advances in identifying preclinical signs of the disease, according to Dr. Daniëlle Gerlag, of the University of Amsterdam in The Netherlands. Dr. Gerlag will discuss possibilities in RA prevention this afternoon.

“If we can identify the people who are at risk and, at that moment, we can intervene and prevent them from developing RA and prevent the pain, the sick leave, the long-term medication, and everything that comes with the disease, then prevention is always better than cure,” Dr. Gerlag said in an interview before her presentation.

Improving capabilities for identifying preclinical signs of RA several years before the symptoms show up presents an opportunity to develop preventive interventions, such as lifestyle changes or prophylactic immunosuppressant treatments being tested in prospective randomised trials already underway.

The first step is to identify those at risk for developing RA, which primarily includes those with first-degree relatives who have the disease. Then those individuals can be screened for circulating antibodies and increased acute phase reactants in their blood, Dr. Gerlag said.

Patients with arthralgia and elevated blood levels of auto-antibodies, such as IgM-rheumatoid factor (RF) and anti-citrullinated protein antibodies (ACPA), have been shown to have a 40% to 70% risk of developing RA within 5 years. Another possible sign of developing RA is asymptomatic synovitis.

Dr. Gerlag said clinical synovitis might be identified through specialised MRI scans or ultrasound scans of the joints, and her team is now looking into the use of PET-CT scans to see if earlier subclinical activity in the joints can be identified.

She has also been investigating biopsies from the knees and ankles of asymptomatic at-risk patients who have circulating antibodies and arthralgia. Those microscopies were normal, however, perhaps because her team might not be sampling the right joints – it is too difficult to take tissue from the smaller hand joints where RA is more common – or perhaps because of timing.

“These people are somewhere on the road from being healthy to having circulating antibodies and having maybe one joint in pain to having full-blown rheumatoid arthritis,” Dr. Gerlag said. “Maybe we’re too early on that road.”
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*COMPANY ST and N* refers to the exhibition space and number.
eular 2013 Exhibit Floor Plan
Convention Centre Floor Plan

North Convention Centre
The **JAK pathways** play an important role in the inflammatory process that leads to joint destruction.

**Discover the intracellular world of Janus kinase (JAK) pathways in RA**

1. Activated immune cells infiltrate the joint and produce pro-inflammatory cytokines.
2. The cytokines bind to cell surface receptors.
3. This activates intracellular signalling pathways such as JAK pathways.
4. The activated JAK proteins activate Stats.
5. Stats translocate to the nucleus and act as transcription factors.
6. The pro-inflammatory protein production triggers the recruitment and activation of additional immune cells. These cells infiltrate the synovium where they cause inflammation and joint destruction, continuing the loop of inflammatory signalling.

**References:**

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Annual European Congress of Rheumatology
Paris, France, 11-14 June 2014

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A magnetic resonance imaging scoring system of joint space narrowing in rheumatoid arthritis showed “a very high” agreement with computed tomography scores and may become a useful tool in rheumatoid arthritis clinical trials after further validation, judging from data to be presented by Dr. Uffe Møller Døhn this afternoon.

In a small study, conducted to validate the "OMERACT-RAMRIS MRI JSN" scoring system in the wrists and metacarpophalangeal (MCP) joints, there was a very high agreement between the joint space narrowing scores on MRI and CT and moderate agreement between scores on MRI and x-ray, according to Dr. Møller Døhn, of Copenhagen University Hospital at Glostrup. In addition, there was “high to very high” inter- and intrareader reliability, particularly for the wrist joints.

An OMERACT (Outcome Measures in Rheumatology) initiative, this scoring system is being developed to provide a more precise and sensitive method of measuring joint space damage in patients with rheumatoid arthritis, but it needs to be validated with comparisons to other imaging methods.

To evaluate the degree of agreement with CT and x-ray scores, this study assessed MRI and CT images of the wrist and the second to fifth metacarpophalangeal (MCP 2-5) joints of 14 people with RA and one healthy control, who were from a clinical trial. Three readers assessed the images twice, and a single reader scored x-rays using the Sharp–Van der Heijde method, said Dr. Møller Døhn, who is in the Center for Rheumatology and Spine Diseases at the hospital.

The MRI scores of joint space narrowing “were very highly correlated” with CT scores, when comparing the wrist and MCP scores both separately and combined. Using intraclass correlation coefficients (ICCs) as a measure of agreement between scores and scorers, the MRI and CT scores for joint space narrowing were 0.94 for the MCP joints, 0.92 for the wrist, and 0.92 for the wrist and MCP joints combined. But the ICCs for the x-ray joint space narrowing scores were lower. With MRI scores, the ICCs were 0.49 for the MCP 2-5 joints and 0.55 for the wrist. With CT scores, the ICCs were 0.56 for the MCP 2-5 joints and 0.53 for the wrist.

“The most important next step is to test the scoring system in a longitudinal setting, in order to investigate the sensitivity to change,” Dr. Møller Døhn said in an earlier interview. “Before the system can be implemented as an outcome measure in clinical trials, we need to know if it is more sensitive than other methods that are already available. If it turns out that [joint space narrowing] assessment of several joints on x-ray is just as good as – or better than – MRI, then it does not add information to what we already use today.”
Ustekinumab Benefit for PsA Sustained Through 1 Year

The lessening of the signs and symptoms of psoriatic arthritis that occurs during the first 6 months of ustekinumab treatment persists and improves further at the end of 1 year, with a favorable safety profile, according to the findings of a study of 312 patients to be discussed this afternoon by Prof. Christopher T. Ritchlin. He will present the 52-week data from the study, the PSUMMIT II trial.

The sustained benefits in American College of Rheumatology (ACR) 20 responses and other efficacy endpoints were evident in patients who had been treated previously with anti-tumor necrosis factor (anti-TNF) agents and among those who were anti-TNF naïve, although the benefits were greater in the anti-TNF naïve patients, Prof. Ritchlin, of the departments of medicine, allergy/immunology, and rheumatology at the University of Rochester, New York, said in an interview.

The PSUMMIT II study is a follow-up to the PSUMMIT I study, the findings of which showed that ustekinumab, a human interleukin (IL)-2 and IL-23 antagonist, was significantly effective in patients with psoriatic arthritis (PsA) who had not been exposed to anti-TNF medications. The PSUMMIT II results show that those patients previously treated with disease-modifying antirheumatic drugs (DMARDs) and/or anti-TNF agents “also get a significant benefit,” which includes beneficial effects on skin and enthesitis, he said.

Ustekinumab is approved in the United States and the European Union for treating moderate to severe plaque psoriasis in adults who are candidates for phototherapy or systemic therapy (in the United States) or those who have failed to respond to, have a contraindication to, or are intolerant to other systemic therapies (in Europe). In December 2012, the manufacturer, Janssen, announced that it had filed for approval for ustekinumab in the United States and Europe for the treatment of active PsA.

The PSUMMIT II study enrolled 312 patients with active PsA who had at least five tender and swollen joints and a C-reactive protein level of at least 0.3 mg/dL; patients who had been treated previously with anti-TNF therapy and those naïve to anti-TNF therapy were included. They were randomized to 45 mg or 90 mg of ustekinumab, administered at 0, 4, and then every 12 weeks, or placebo. At 16 weeks, those with less than a 5% improvement in tender and swollen joint counts on placebo were switched to the 45-mg dose, those on 45 mg were switched to 90 mg, and those on 90 mg remained on that dose.

At 6 months, significantly more patients on ustekinumab than those on placebo achieved an ACR 20 result, the primary endpoint, and more patients on ustekinumab had ACR 50 and at least a 75% improvement in the Psoriasis Area and Severity Index (PASI 75).

At 1 year, Prof. Ritchlin said that these results were sustained, with 47%-48% of those on 45 mg and 90 mg, and 56% of those who switched from placebo to the 45-mg dose, achieving an ACR 20. In addition, 26%-29% achieved an ACR 50, and 13%-18% achieved an ACR 70. There were also improvements associated with treatment in HAQ-DI (Health Assessment Questionnaire–Disability Index) scores at week 52.

Among those who had not been treated before with an anti-TNF agent, 59%-73% of those on ustekinumab achieved an ACR 20 at week 52, compared with 37%-41% of those who had taken an anti-TNF agent previously. Although responses among anti-TNF naïve patients were superior, the responses among those who had been treated with these agents previously were still significantly improved, an indication that ustekinumab “offers an alternative for patients who cannot take or fail anti-TNF agents,” Dr. Ritchlin said in the interview.

Treatment was “very effective” for skin symptoms and for enthesitis, he noted. Enthesitis—among those with enthesitis at baseline—improved by 95% among those on the 45-mg dose, 91% among those on the 90-mg dose, and 100% among those who switched from placebo to the 45-mg dose of ustekinumab. In these three patient groups, whose baseline PASI scores ranged from 11 to 13, PASI 75 scores improved by 56%-64%.

In general, ustekinumab was well tolerated, with no deaths or cases of tuberculous reported—and with similar rates of adverse events and serious adverse events between the two doses (almost 6%). There were two malignancies: one breast cancer and one squamous cell carcinoma in two patients on ustekinumab, who had been treated with anti-TNFs previously. The rate of serious infections was less than 1% among those on ustekinumab. Through 60 weeks of treatment, there were three major adverse cardiovascular events, all myocardial infarctions, in patients treated with ustekinumab, who also had multiple cardiovascular risk factors and had been on anti-TNF treatment previously.

Prof. Ritchlin disclosed having received grant and research support from Janssen R&D; four of the nine remaining authors are Janssen employees and shareholders of Johnson & Johnson, Janssen’s parent company. Ustekinumab is marketed as Stelara in the United States.
Will doing these activities be challenging for your digital ulcer patients?

Come to Stand 57 and let’s talk

Digital ulcers (DUs) are a frequent and persistent problem for patients with systemic sclerosis (SSc)\textsuperscript{1,2} and can significantly impact their quality of life.\textsuperscript{3-11}

Here on stand 57, hall 10 we’re talking not only about a clinical management approach to help reduce the burden of this debilitating condition, but also about earlier detection via capillaroscopy.

To find out more and get some hands on experience with capillaroscopy, come and join us during exhibition times.

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A visitor seeking to get fully in touch with Spain’s vibrant medical history would have to go on a tour of the country, visiting such diverse cities as Seville, Toledo, and Valladolid, among others. But a good place to start is certainly the city of Madrid.

For even before it became Spain’s capital in 1561, at the decision of Philip II (of Spanish Armada fame), Madrid was home to a rich medical tradition, in part an inheritance from its Moorish past. The presence of the royal court thereafter only heightened the importance and development of medicine in the city. Many relevant historical sites are still available for visitors to view.

Physicians were held in exceptionally high esteem in 15th-century Spain, and in fact, they had their own special tribunals of justice from 1422 on, separate from the regular arm of law, which could not be interfered with by any civilian or other authority.

This was in part a result of the patronage of the Spanish Crown, which maintained a long relationship with some of the most celebrated physicians in Spain.

Among the most notable of these court physicians was the celebrated anatomist Vesalius, who, in the last decade of his life, served as physician to Philip II, who was responsible for much of the early reorganisation of the Spanish medical establishment, in particular the hospitals.

There were 11 major medical institutions in early Madrid, including the Hospital del Campo del Rey (founded before 1421), which contained 12 beds for women; the Hospital de San Antón (1438); the Hospital de Santa Catalina de los Donados (1467), which provided relief to “honest elderly artisans”; and the Hospital de Beatriz Galindo (1500), organising relief for 12 lay sick people and for 6 priests or other people “of quality.”

These were among the hospitals consolidated by Philip II in 1587, leaving Madrid with four hospitals, the largest being the newly created General Hospital, which centralised hospital facilities for the Spanish Court.

By the 18th century, King Carlos III decided to expand the hospital, and it was significantly remodeled...
Tracleer® (bosentan)

**Abbreviated Prescribing Information**

(See full SmPC before prescribing)

**Tracleer 62.5 mg and 125 mg dispersible tablets:** 32 mg of bosentan for oral use.

**Uses**

Treatment of pulmonary arterial hypertension (PAH) to improve exercise capacity and symptoms in patients with WHO functional class III or IV. Tracleer has also been shown to be effective in patients with PAH with Eisenmenger’s physiology. Symptoms in patients with PAH WHO functional class II have not been studied.

Tracleer® is also indicated to reduce the number of new digital ulcers in patients with systemic sclerosis and ongoing digital ulcers.

**Disuse and administration**

Treatment should only be initiated and monitored by a physician experienced in the treatment of PAH or systemic disorders. Tablets are to be taken only morning and evening, with or without food. The dispensible tablets should be added to a little water on the palm, and the liquid to arterial dilatation, before swallowing. If necessary the dispersible tablet should be added to water along the break-marks. The dispersible tablet has been stratified only in paediatric patients with PAH. Treatment should be initiated at a dose of 62.5 mg twice daily for 4 weeks and then increased to 125 mg twice daily after an additional 4 to 8 weeks. If the patient is responding well to 125 mg twice daily of Tracleer may slightly improve their exercise capacity when the dose is increased to 250 mg twice daily. A clinical evaluation and assessment that the liver function is dose-dependent. If the decision to withdraw Tracleer is taken, it should be done gradually while an alternative therapy is introduced. Controlled clinical trial experience in patients with digital ulcers associated with systemic sclerosis or limited to 0–6 months and there are no data on the safety and efficacy in patients of the age of 18 years. The digital ulcer patient’s response to treatment with Tracleer had been shown to be dose-related and that the patient should be re-evaluated for increased benefit and empirical evidence. No dose adjustment required. Rare: Synpasis®

**Special warnings and precautions for use**

The efficacy of Tracleer has not been established in patients with severe pulmonary artery hypertension, hypotension and to liver function tests. An increased long-term risk of hepatic toxicity and haematological adverse events cannot be excluded with bosentan and 0.3% (6 patients) on placebo.

**Liver function**

Elevations in liver amonotransferases (AST and/or ALT) need to be considered in patients who have a liver disorder. In a specific study has been performed. It is recommended that patients be monitored for signs of fluid retention. Should this occur continue or re-introducing Tracleer according to the conditions described below. The reason for treatment discontinuation of the patients treated before outweigh the potential risks and when liver amonotransferases levels are within pre-treatment values. The incidence of a haematological abnormality cannot be used as an indicator of the patient's response to treatment with Tracleer. bosentan is used in combination with antiretroviral medicinal products. Due to potential for interactions and to liver function tests. An increased long-term risk of hepatic toxicity and haematological adverse events cannot be excluded with bosentan and 0.3% (6 patients) on placebo.

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**Erythema**

Erythema is a common adverse event observed in patients treated with bosentan. Erythema is a common adverse event observed in patients treated with bosentan.

**Hypersensitivity reactions**

Hypersensitivity reactions (including dermatitis, pruritus and rash)2

**Cardiac disorders**

Common: Palpitation1

**Adequate contraception**

Before the initiation of Tracleer treatment in women of child-bearing potential, the absence of pregnancy should be confirmed by a negative pregnancy test. Women of child-bearing potential cannot use hormonal contraceptives ineffective. Therefore, women of child-bearing potential must not use hormonal contraception and have a negative pre-treatment pregnancy test. Before the initiation of Tracleer treatment, the digital ulcers in patients with systemic sclerosis and ongoing digital ulcers.

**Skin and subcutaneous disorders**

Common: Erythema

**General disorders and administration site conditions**

Common: Oedema, fluid retention2

**Legal category**

Prescription Only Medicine

**Date of PI preparation**

November 2012

**Qualitative and quantitative composition**

Each film-coated tablet contains 62.5 mg or 125 mg bosentan (as monohydrate). Each dispersible tablet contains 32 mg bosentan (as monohydrate). Excerpt: 3.7 mg of AEs (95%) are present in each dispersible tablet other excipients Tracleer 62.5 mg and 125 mg film-coated tablets.

**Legal category**

Prescription Only Medicine

**Data of PI preparation**

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Continued from page 19

by the famous architect Francesco Sabatini. The hospital was in service until 1665, and in 1777, it was declared a national monument because of its historic and artistic value. Restoration began in 1980, and in 1986 the Reina Sofia Art Museum opened there.

One of Spain’s most important medical fraternities and research societies, the Royal National Medical Academy, founded in 1733, is still an active force. Approved by royal decree in 1734, the Academy was founded in Madrid and directed by Joseph Cervi, who was one of the most eminent physicians in service to the Spanish Court.

Surgeons, as compared with regular physicians, were originally not held in high esteem, being mere barbers for the majority of this early period.

The first college of surgery in Spain was not founded until 1748 in Cadiz, with the second in Barcelona (1764), and the third in Madrid in 1779.

Some of the history of medicine’s more interesting medical figures came from Spain, many of whom had their careers launched in or associated with Madrid.

One of the more interesting figures, physician and army surgeon Francisco Xavier Balmis, spares the global empire that gave Spain generations of world hegemony. He brought the vaccine revolution to the Spanish New World in a fashion similar to that which Edward Jenner wrought for English North America.

By order of King Carlos IV, the “Real Expedición Filantrópica de la Vacuna” (royal philanthropic expedition of the smallpox vaccine), under the medical command of Dr. Balmis, embarked from Spain in 1803 with the aim of sailing round the world and spreading the use of Jenner’s smallpox vaccine to all the Spanish possessions in the New World and Asia.

On board the corvette “María Pita” with Dr. Balmis were three surgeons, two first-aid practitioners, four male nurses, and 22 boys, aged 8-10 years old from an orphanage and carried 2,000 copies of Dr. Balmis’s translation of Moreau de la Sarthe’s book on vaccines, which were to be handed out to medical and political authorities wherever they landed.

Perhaps the most interesting medical aspect of the long voyage was the way the live vaccine was maintained during the journey. The initial vaccination was performed in Madrid and carried on to the port of debarkation through sequential vaccination in five of the orphans. During the voyage itself, Dr. Balmis and his associates sequentially vaccinated the 22 boys kept on board arm every 9 or 10 days, thereby maintaining a viable transmission chain.

His voyage of vaccination visited ports in the Caribbean and South, Central, and North America, reaching up to San Antonio, Texas, U.S.A. They then travelled to the Philippines, Macao, among other destinations, landing back in Spain in 1806.

Upon his return, Dr. Balmis was made Inspector General of Vaccination for Spain and the Indies.

At the height of Spain’s Golden Age, the importance of medicine and a curiosity about human anatomy fueled the interests of some of Spain’s most renowned artists, as shown by many paintings housed in Madrid’s Museo del Prado, home to one of the world’s great collections of art. These include works by the famed painter Diego Velázquez, depicting a wide variety of then more common medical conditions, including achondroplasia, cretinism, hydrocephalus, and osteitis deformans.

He also had a special fascination, as did many Renaissance painters, with dwarfism, a condition he portrayed with then uncharacteristic dignity and respect. The Prado also features Carreño de Miranda’s similar representations, including those of endocrine obesity.

Visitors to Madrid can also explore the historical Real Oficina de Farmacia (Royal Pharmacy), one of the oldest in Europe, located in a wing of the Royal Palace in Madrid. It was wholly dedicated to attending to Spain’s royal family for several centuries. At a less august level, there is also a Museum of Military Pharmacy in Madrid, run by the Spanish Defense Department, which opened in 1928 and is available for viewing by appointment.

In addition, the History Museum in Madrid is housed in the former Real Hospicio de San Fernando, and is an entrance crafted by Pedro de Ribera in the 1720s, and is considered one of the finest examples of baroque architecture in the city.

The Real Oficina de Farmacia, located in the royal palace, is one of the oldest pharmacies in Europe.

Ham: A Spanish Delight Worth Your Attention

A delicious Spanish ham can be 2 years in the making, but it definitely worth the wait. You can see them all over Madrid, hanging in the stalls in the outdoor markets and from the rafters in restaurants. Just say: Yes, yes, yes to their singular taste. Without a slice or two of ham on your plate, you have not had the complete experience of Madrid.
Satellite Programme Wednesday 12 June 2013

13:00 – 14:30 Pfizer Hall 7
Treating Early for Long-Term Success: The PRIZE in RA
Chair: T. Kvien, Norway
13:00 – 13:05
Welcome and introduction
T. Kvien, Norway
13:05 – 13:25
Early intervention for optimal outcomes
P. Emery, UK
13:25 – 13:45
Considerations for maintaining clinical response
X. Mariette, France
13:45 – 14:05
Tailoring patient support to achieve treatment success
R. Horne, UK
14:05 – 14:15
Personalising therapy for long-term outcomes
T. Kvien, Norway
14:15 – 14:25
Panel discussion
All
14:25 – 14:30
Summary and close
T. Kvien, Norway

13:00 – 14:30 AbbVie N103/N104
Treating Axial SpA to Target: A New Clinical Challenge
Chair: D. van der Heijde, Netherlands
13:00 – 13:05
Welcome
D. van der Heijde, Netherlands
13:05 – 13:20
Learning from experience in RA: Impact of treatment-to-target (T2T) in daily clinical practice
J. S. Smolen, Austria
13:20 – 13:35
Development and clinical implications of SpA T2T recommendations
D. van der Heijde, Netherlands
13:35 – 13:50
Treatment of patients with axial SpA today: A clinical perspective
D. Elewaut, Belgium
13:50 – 14:05
Optimising the management of patients with axial SpA: Current treatment options
J. Sieper, Germany
14:05 – 14:30
Panel discussion
All
14:30 - Close

13:00 – 14:30 International Medical Press Hall 4
Reducing Cardiovascular Risk in RA: Current and Future Perspectives
Chair: E. Choy, UK
13:00 – 13:05
Introduction and welcome
E. Choy, UK
13:05 – 13:25
CVI in RA: the role of cytokines and systemic inflammation
E. Choy, UK
13:25 – 13:45
Inflammation and lipids, their roles as CV risk factors in RA
M. Nurmohamed, Netherlands
13:45 – 14:05
RA patients and CVD: Assessing risk and improving outcomes
M. A. González-Gay, Spain
14:05 – 14:25
Managing CVD patients with RA: Special considerations
A. G. Semb, Norway
14:25 – 14:30
Discussion
All

13:00 – 14:30 Costello Medical Consulting N105/N106
Non-Radiographic Axial Spondyloarthritis: Values and Controversies
Chair: R. Landewé, Netherlands
13:00 – 13:10
Welcome and Introduction
R. Landewé, Netherlands
13:10 – 13:30
Non-radiographic axSpA: Clinical Diagnosis or Classification?
M. Rudwaleit, Germany
13:30 – 13:50
Value and Dangers of Magnetic Resonance Imaging in Non-radiographic axSpA
W. Maksymowych, Canada
13:50 – 14:10
Why is Non-radiographic axSpA Different from Fibromyalgia?
F. van den Bosch, Belgium
14:10 – 14:30
Question and Answer Session
All

13:00 – 14:30 Menarini Retiro
Gout: Multiple Clinical Outcomes
Chairs: T. Bardin, France & F. Perez-Ruiz, Spain
13:00 – 13:05
Introduction
T. Bardin, France
13:05 – 13:20
Diagnostic procedures in gout
L. Punzi, Italy
13:20 – 13:40
From podagra to a systemic chronic disease
F. Perez-Ruiz, Spain
13:40 – 14:00
XOIs to fine tune hyperuricemia impact on gouty patients
T. Bardin, France
14:00 – 14:20
Gout and renal impairment: A frequent and hard to manage duo
P. Richette, France
14:20 – 14:30
Discussion
Other Opportunistic Infections

Tuberculosis

• Physicians should exercise caution when considering HUMIRA in patients with a history of recurring infection or with underlying risk factors for tuberculosis. Patients who develop a new infection while taking HUMIRA should be monitored closely and undergo a complete diagnostic evaluation.

Polyarteritis Nodosa

• Patients who develop a new infection while taking HUMIRA should be monitored closely and undergo a complete diagnostic evaluation.

Hypersensitivity to the active substance or to any of the excipients

• Hypersensitivity to the active substance or to any of the excipients

Other Serious Infections

• Other serious infections seen in clinical trials include pneumonia, pyelonephritis, esophageal or anastomotic leaks, cellulitis, S. aureus infections, and sepsis. These infections are more likely to occur in patients who have medical contraindications for such therapies.

Contraindications

• Contraindications

Hematologic Reactions

• Rare reports of pancytopenia, including aplastic anaemia, have been reported with TNF-antagonist agents.

Immunosuppression

• It is recommended that polyarticular JIA patients, if possible, be brought up to date with all immunizations in agreement with current immunization guidelines prior to initiating HUMIRA therapy.

Vaccinations

• Similar antibody responses to the standard 23-valent pneumococcal vaccine and the influenza trivalent virus vaccination were observed in patients who were treated with HUMIRA or placebo. Data are not available on the secondary transmission of infection by live vaccines in patients receiving HUMIRA.

• It is recommended that polyarticular JIA patients, if possible, be brought up to date with all immunizations in agreement with current immunization guidelines prior to initiating HUMIRA therapy.

Hematologic Reactions

• Rare reports of pancytopenia, including aplastic anaemia, have been reported with TNF-antagonist agents.

• All patients should be advised to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias while on HUMIRA.

• Discontinuation of HUMIRA therapy should be considered in patients with confirmed significant hematologic abnormalities.

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TRUST in HUMIRA
An unmatched legacy.

10 YEARS OF EFFICACY DATA FOR RA IN LABEL* 9 INDICATIONS†

15 YEARS OF CLINICAL TRIAL EXPERIENCE, BEGINNING WITH RHEUMATOID ARTHRITIS (RA)‡

71 CLINICAL TRIALS IN THE LARGEST PUBLISHED ANTI-TUMOUR NECROSIS FACTOR (TNF) CROSS-INDICATION SAFETY DATABASE§

MORE THAN 23,000 PATIENTS IN GLOBAL CLINICAL STUDIES§

*Rheumatoid Arthritis (RA)
HUMIRA, in combination with methotrexate, is indicated for:
• The treatment of moderate to severe active RA in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate, has been inadequate.
• The treatment of severe active and progressive RA in adults not previously treated with methotrexate.
HUMIRA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.
HUMIRA has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

†First person dosed in April 1997.

References: 1. HUMIRA [summary of product characteristics]. AbbVie Inc.; April 2013.

Please note: Not all indications are approved in all countries.

Please see Important Treatment Considerations on reverse.

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