

## Motivation and Mission

With our MDS Newsletter - here in its first issue -, we aim to bundle and promote the exchange and knowledge of clinical research, diagnostics and therapy of the myelodysplastic syndromes (MDS).

This newsletter is particularly directed towards doctors, scientists and personnel of the pharmaceutical industry.

We provide information about different topics such as current clinical trials, new methods of diagnosis and treatment options, research reports as well as current events regarding the MDS disorder.

Our editors are always interested in scientific and informative articles about MDS.

Your MDS Newsletter team

## Intro EMSCO - the European Myelodysplastic Syndrome Coordinating Office

Clinical research is the key to medical progress. At the same time, clinical studies must meet high ethical, legal, methodical and scientific requirements.

A great level of coordination and organisation effort is therefore necessary to guarantee professional work. The integration of several

medical centres for clinical studies sets high demands for all study participants involved regarding organisation, monitoring, control of success, documentation and assessment. Pharmaceutical companies and study centres therefore increasingly resort to coordinating offices for clinical studies.

The coordinating office EMSCO (European Myelodysplastic Syndrome Coordinating Office) was founded at the beginning of 2013 for the coordination of clinical MDS studies in particular. This office is affiliated with the GMIHO mbh, which operates as sponsor and service platform for clinical studies in the field of haematology and oncology.

As central contact point, EMSCO supports the European cooperation of scientists, study groups and the MDS industry and therefore contributes towards transparency and profitability for research and patients.



Figure 1: Screenshot of the website www.emsco.eu

## LEMON-5

### Lenalidomid

A DMC conference about the safety analysis after 50 completed patients took place on 17.07.2013. The minutes of the meeting will be published in a separate newsletter. The treatment of the remaining 41 patients will be completed by 31.03.2014 at the latest. A safety analysis by the DMC will follow.

## Disclaimer

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Incorporated

The services of EMSCO include the production of study designs, documentation of clinical studies, support of study participants regarding necessary documents and forms, drafting and signing of contracts and mostly the coordination of clinical studies and projects in the field of MDS.

By bundling the competences and studies, EMSCO aims to standardise documents, forms and SOPs in the field of MDS studies. The primary objective is, however, to increase the amount of clinical studies in Germany.

## Preannouncement: 2<sup>nd</sup> French-German MDS Workshop

For the second time already, the French and German MDS study group meets to discuss recent diagnostic and therapeutic strategies of MDS.

The second French-German MDS Workshop will take place in Paris from September 18 to 19, 2013. The workshop is organised by the French study group.

The GMIHO mbh organises the Kick-Off-Meeting of EMSCO in the course of the second French-German MDS workshop. We are happy to announce Celgene GmbH and Baxter Oncology GmbH as sponsors of this event.

Moreover, EMSCO organises special events such as conferences, symposia, workshops as well as strategic progress meetings for scientists and the pharmaceutical industry.

For further information, please refer to [www.emsco.eu](http://www.emsco.eu)

Author: D. Lippmann

## Diagnosis MDS – web service provides help for doctors

The symptoms of MDS are generally not specific. Therefore, a precise diagnosis can only be given by a selective examination of blood and bone marrow.

A profound diagnosis may be difficult nevertheless, even amongst experts with many years of experience in the field. The diagnosis can have decisive effects regarding the therapy to be applied. A precise diagnosis and evaluation of prognoses are important therefore.

For this purpose, a new website has been created to assist doctors in finding a safe diagnosis and prognoses of the MDS disorder.

Besides consultative diagnostic tools, this diagnosis website also offers ongoing training as well as an exclusive interactive training programme for diagnosticians to promote the state of knowledge amongst experts.



Figure 2: Screenshot of the website [www.mdsdiagnosis.com](http://www.mdsdiagnosis.com)

This web service aims to strongly connect specialists in the field of MDS and to exchange and expand relevant knowledge.

This communication platform sets a further milestone in the research of the course of MDS and promotes efficient teamwork.

The website is already online. You are welcome to register at [www.mdsdiagnosis.com](http://www.mdsdiagnosis.com).

Author: S. Faber

## Approval of lenalidomide for low-risk MDS with del(5q)

With the further development of thalidomide, a new group of substances, the "immunomodulatory derivatives" (ImiDs) were created. Lenalidomide is a part of this group.

However, this substance had not been approved by the EMA in Europe up to now, because some patient data suggested that lenalidomide could possibly increase the incidence of AML from a low-risk MDS with del(5q). Analyses of several groups with pooled del(5q) MDS patients (IPSS LOW/INT-1), which mostly received supporting treatment only, have shown a "natural" progress into an AML of approx. 20% after 5 years (Kelaidi et al, 2010; Mallo et al, 2011; Germing et al, 2011). Additionally, a recently published retrospective and comparative

study (figure 3) could prove that the AML transfer is not influenced by lenalidomide (Kuendgen et al).

Fortunately, the new results have now led to the approval of lenalidomide by the EMA for the transfusion-required low-risk MDS (IPSS LOW/INT-1) with singular del(5q) in Europe a few weeks ago.

A large randomised study about Low/Int-1 MDS patients without del(5q) has also been completed recently, which should lead to the approval of the substance. However, the results are not expected for approximately another year.

Author: U. Platzbecker

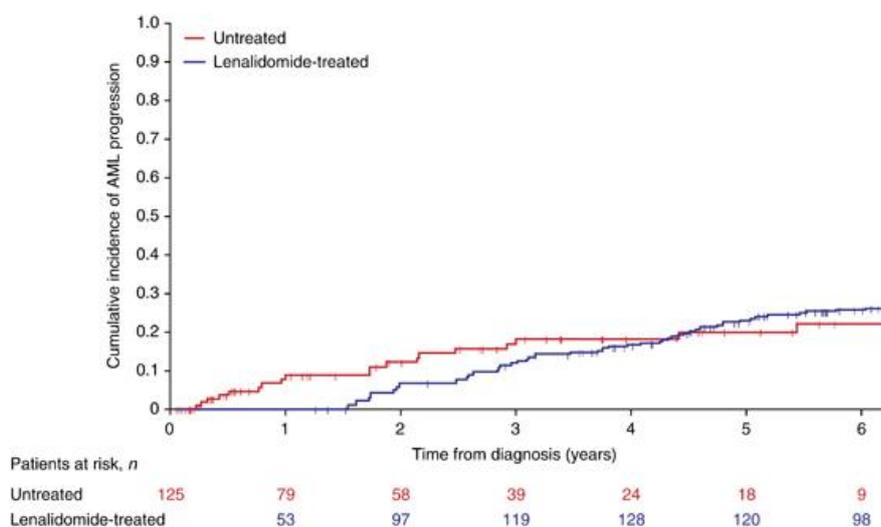


Figure 3: Retrospective comparison of AML progression of patients with IPSS low/int-1 and del(5q) with or without lenalidomide therapy (Kuendgen et al)

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## MDS register – the place to go for study groups

To fight a disease successfully, it is important to characterise it biologically, to predict its course as precisely as possible and to find the best suitable therapy for patients.

Starting in 2002, the initiative of clinical study centres, scientists and doctors strives for a closer cooperation in the field of MDS.

The goals of a cooperation include a coherent documentation of courses of patients with MDS disorder, the implementation of uniform cytomorphologic and cytogenetic diagnostics, the joint execution of clinical studies as well as mutual support for experimental and scientific projects and prognosis research.

A uniform communication platform had to be established for a well-aimed scientific exchange. Therefore, the MDS register in Düsseldorf had been used as model for a multicentre, decentralised register. The website provides an overview of the clinics involved in the cooperation, respective contact persons, scientific projects as well as diagnostic and prognostic classifications and clinical studies, delivery notes for diagnosticians, cooperation partners and literature.

Annual meetings between the German MDS study group and the Groupe

Française de Myelodysplasie will encourage this exchange. New projects in this field will result from these annual meetings.



This year, the annual meeting will take place at the Düsseldorf University Hospital on September 29, 2013. For more information about the MDS register initiative, the MDS meeting, other special events and MDS in general, please refer to [www.mds-register.de](http://www.mds-register.de).

The MDS register is supported by



Author: K. Bodin, D. Lippmann

## Event recommendations

**The Dresden Symposium for Haematology and Oncology 2013**. September 6 to 8, 2013 | Radisson Blu Park Hotel & Conference Center, Radebeul near Dresden

**Annual Meeting 2013 of the German-Austrian-Swiss MDS study group**  
25. September 25, 2013 | Düsseldorf University Hospital

**DGHO Annual Meeting 2013**  
18. October 18 to 22, 2013 | Vienna

**Progress in Acute Myeloid Leukemia, Myelodysplastic Syndromes and Acute Lymphoblastic Leukemia: Classification and Molecular Pathogenesis**  
October 24 to 26, 2013 | The University of Texas MD Anderson Cancer Center

**ESH International Conference on Haematological Disorders in the Elderly**  
6. November 6 to 7, 2013 | Barcelona

**2013 ASH Annual Meeting and Exposition**  
7. December 7 to 10, 2013 | Ernest N. Morial Convention Center, New Orleans