



AA & MDS International Foundation
Electronic Bulletin
July 2005

FDA Grants Priority Review for Celgene's REVLIMID® (lenalidomide) New Drug Application, Review/Decision Expected by October 7, 2005

Celgene Corporation announced in their June 21, 2005 press release that the U.S. Food and Drug Administration (FDA) has granted priority review designation to its New Drug Application (NDA) for REVLIMID® based on [Phase II clinical trial data](#). Celgene is seeking approval to market Revlimid® as a treatment for transfusion-dependent MDS patients with 5q deletion chromosomal abnormality. NDAs with priority review receive expedited treatment, with the target review period for the application reduced from ten months to six months. The FDA expects to complete their review and decision by October 7, 2005 after an FDA review team has evaluated whether the clinical trial data the sponsor submitted show that the drug is safe and effective for its proposed use. Read more in Celgene's press release at www.celgene.com. Learn about FDA's Drug Approval Process at www.fda.gov. Click here to view information about Revlimid® from our [Drug Information Page](#). Click here to view [AA&MDSIF's Clinical Trials Listing](#).

FDA Grants Priority Review for EXJADE® (deferasirox) Once-Daily Oral Iron Chelator for Treatment of Chronic Iron Overload Due to Blood Transfusions

- Novartis Oncology announced in their press release on June 22, 2005 that its New Drug Application (NDA) for Exjade® (deferasirox) has been granted priority review by the U.S. Food and Drug Administration (FDA). Exjade® is a once-daily oral iron chelator for the treatment of chronic iron overload due to blood transfusions. A priority review establishes an action date no later than six months after the submission date; the Exjade® NDA was submitted in May 2005. Exjade, also known as investigational agent ICL670, was granted priority review in Australia and fast track status in Switzerland. Further, Exjade received Orphan Drug status in the U.S., Europe and Australia. Read more in the Novartis press release at www.novartis.com. Learn about FDA's Drug Approval Process at www.fda.gov. Click here to view [AA&MDSIF's Clinical Trials Listing](#).

2005 Patient Conference - Hurry and Book Today! Hotel Room Rates Increase on July 14th

- Over 200 patients and families will be gathering in Denver, Colorado on July 28th – 30th to network together and hear the latest in treatment and research updates from several of the leading medical experts. Visit www.aamds.org for [first come, first served FREE registration](#) today! Or call the AA&MDSIF Office at (800) 747-2820. We hope to see you there!

Act Now! Support Congressional Resolution 179 to help to raise greater awareness of Aplastic Anemia, MDS and PNH!

We need each and every AA&MDSIF supporter to spring into action! In order for us to get [Resolution 179](#) passed through Congress, we need to generate as much congressional support as possible. In order to create this support, please contact your congressperson immediately and ask your family, friends, and coworkers to do the same.

1. Visit www.house.gov to find out how to contact your congressional representative.
2. Contact your congressperson and tell him or her how important Resolution 179 is to you.
3. Ask your congressperson to call Sherrod Brown and Michael Bilirakis's office to say they support Resolution 179. (You should not call Sherrod Brown or Michael Bilirakis's office - Only congressional representatives should call them to say they support the resolution. And please note that we are only contacting U.S. Representatives at this time; we are not lobbying U.S. Senators.)

Enactment of this resolution will encourage the federal government to fund research and engage in public health initiatives that will improve treatment and lead to cures for bone marrow diseases.

We need your help to make this happen!

Wear Your "Bravery" Bracelet ~ Show you Support the Quest to Cure Bone Marrow Diseases!

You've seen yellow, you've seen pink...now wear our red and white wristbands symbolizing red & white blood cells! With the word "Bravery" inscribed as a reminder of the daily courage our patients and their loved ones demonstrate, these bracelets show the world how important it is to find effective treatments and ultimately cure these devastating diseases. Make more people aware ~ ask your friends, family, and colleagues to wear "Bravery" bracelets in support of AA&MDSIF, knowing the Foundation leads the fight to cure bone marrow failure diseases. We have thousands on hand, so order generously! Place your bulk order today at <http://www.aplastic.org/help.shtml> or call (800)747-2820.



This e-bulletin is published by
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