

## IBM drug BYM338

An article by Bloomberg News March 5 quotes Simon Moroney, chief executive officer of MorphoSys, the company that developed the drug BYM338 for Novartis. Moroney spoke at an investor event in Munich.

According to Bloomberg's report, Moroney said Novartis plans to ask regulators for permission to market the drug to treat sporadic inclusion body myositis as early as 2016.

The drug is currently being tested to also treat other illnesses, and the largest share of sales will probably be from ailments such as cachexia, the weight and muscle loss that's often found in patients with illnesses such as cancer and chronic obstructive pulmonary disease, Moroney said.

There are 36 study locations presently, including two locations that have begun recruitment in the United States. Those in the U.S. now recruiting are:

Neuromuscular Research Center  
Phoenix, Arizona 85028  
Contact: K. Sivakumar

Nerve & Muscle Center of Texas  
Houston, Texas 77030

Contact: A. Shaibani

Other centers listed on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) as "not yet recruiting" are in Orange, CA; Sacramento, CA; Miami, FL; Kansas City, KS; Baltimore, MD; Boston, MA; Columbus, OH; Portland, OR, and Dallas, TX.

Those interested in being considered for recruitment at any domestic sites—whether presently recruiting or not—should call 888-669-6682. Although progress has been stalled for several months, some applicants in California have been sent the study protocol to consider whether they wish to be included.

Find sites in Europe, Asia and Australia at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). To see the list in its entirety, click on the drop-down menu.

To help TMA track participation and provide accurate information on this historic study, we would appreciate knowing if you join the trial. TMA will continue to update its members on the trial status.



## What does "improvement" mean to you?

In June, myositis investigators from all over the world will meet in Paris to develop improved myositis response criteria for use in future myositis clinical trials. In this session, the last of a number of such meetings, international myositis experts will hammer out a consensus. This is extremely important to researchers, who need some way to measure whether a particular drug or other treatment has indeed altered the disease course of those in the trial.

Researchers will reach an agreement on what constitutes clinically significant improvement, and, for the first time, set criteria for major clinical response for myositis. Researchers are also seeking comments from patients on what they would consider improvement and major clinical response. If you would like to make a comment, please email [tma@myositis.org](mailto:tma@myositis.org).