



**Celgene Corporation**  
86 Morris Avenue  
Summit, New Jersey 07901

October 19, 2017

**RE: Mongersen (GED-0301 Phase 3 ROADS Program Trials)**

Dear ROADS program Investigator,

We regret to inform you that based upon the recommendation of the external Data Monitoring Committee (DMC), the mongersen REVOLVE (GED-0301-CD-002) and the SUSTAIN (GED-0301-CD-004) trials in Crohn's disease are being discontinued effective immediately. Celgene has also decided to not initiate the DEFINE (GED-0301-CD-003) trial in Crohn's disease.

The DMC recommendation was based upon the lack of emerging benefit during their recent review of unblinded data. Importantly, their recommendation to terminate the trial was not based upon new emergent safety findings.

The Celgene team requests that you initiate the following actions to discontinue these trials:

- No new patients are to be screened or enrolled. IVR has been disabled for screening and enrollment of new patients.
- All patients in screening are to be withdrawn. These patients should be verbally informed regarding the discontinuation of the trials.
- All active patients should be verbally informed regarding the discontinuation of the trials and should discontinue all study treatments.
- All active patients should proceed with the early termination visit as soon as feasible. All assessments should be conducted and documented as described in the protocol for this visit. The ileocolonoscopy does not need to be performed.
- Notify your local IRBs and ECs, as applicable, as soon as feasible regarding these decisions. In parallel, Celgene and Quintiles will inform all Health Authorities, central IRBs and central ECs globally.
- Please ensure that all communications are properly documented in your source files.

Thank you for your hard work in support of the mongersen GED-0301 ROADS program. The study team would like to thank you for your efforts and participation in these trials. Your diligence in adhering to the trial protocols, and the integrity with which you have performed the trials and treated participating patients is greatly valued.

While we are disappointed in these results from REVOLVE and SUSTAIN, Celgene remains committed to advancing our portfolio of novel medicines for patients suffering from inflammatory bowel disease. Celgene will keep you and your study teams updated about any further developments.

If you have any operational questions related to the trial discontinuation process, please contact your study site monitor.

If you have questions regarding this communication, please do not hesitate to contact the Celgene clinical team.

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