Unit B1, Westacott Business Centre
Westacott Way, Littlewick Green
Maidenhead, SL6 6AR
Phone: [redacted]

Ms. Kate Moore
Technology Appraisal Project Manager
National Institute for
Health and Clinical Excellence

Level 1A, City Tower
Piccadilly Plaza
Manchester
M1 4BD

12th November, 2010

Dear Kate,

NRAS response to 2nd Appraisal consultation document

Golimumab for the treatment of rheumatoid arthritis after the failure of previous disease-modifying anti-rheumatic drugs

Thank you for the opportunity to contribute to the second ACD in respect of Golimumab for for the treatement of Rheumatoid Arthritis after the failure of previous disease modifying anti-rheumatic drugs.

Has all of the relevant evidence been taken into account?
We cannot comment on the trial data other than to say that golimumab appears to be as effective and as safe as other Anti-TNF treatments currently in use in the NHS. From a patient perspective, however, its administration is of interest and potential advantage over other TNFs, as a subcutaneous injection once a month as opposed to more frequently than that is likely to be preferable to patients, especially those for whom the prospect of self injecting is difficult and causing anxiety. There is a convenient injector pen and the preparation seems less likely to sting on injection than some other biologics available which may also be a factor which could be of importance to patients.

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
We cannot comment on the above, other than to say that golimumab appears to be comparable to other TNFs approved by NICE in terms of clinical and cost effectiveness.

Are the provisional recommendations sound and a suitable basis for guidance to the NHS?
We hope that the Appraisal Committee will reconsider their 'minded not to' recommend interim guidance.

Whilst TNFs are generally considered by NICE in a 'class' way, it should be stated that they all work differently and due to the heterogeneity of RA, one cannot assume that because drug A works for one patient that it will automatically work for the next. This is why we need access to the whole range of biologic therapies but have clear starting and stopping rules. Golimumab has been shown to be effective in all its clinical trials and to improve QoL for patients who have failed standard DMARD therapy. We know from BSR Biologics Register data that approx. 30% - 50% of patients will either fail immediately or will ultimately fail on the 4 existing TNF therapies and it is vital that we have other biologic therapies available to treat these patients who, by the nature of their eligibility for TNF in the first place, demonstrates the serious and refractory nature of their disease.

Golimumab has been shown to give sustained benefit over the longer term and is a welcome addition to the armamentarium of biologic therapies necessary to treat people with moderate to severe RA. This technology has the advantage of being able to be administered by the patient in their own home once every 4 weeks whereas other subcutaneous TNF options are more frequently administered. Currently for patients who are sero-negative (about 25-30% of all RA patients), Rituximab is a less attractive and less effective option for this group and therefore, golimumab would be a suitable option.

It is important that we gain clinical experience with this drug which is less likely to occur unless NICE recommend it for use.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?
I am not aware of any.

Finally we would like to say that the BSR has published a guideline on eligibility criteria to go onto and to stay on biologic therapy which we have contributed to and support. The most important element of these recommendations argues that the current eligibility criteria are set too high and the paper provides the evidence-based arguments for reducing the DAS 28 from the current 5.1 to 3.2 and that the new criteria should be applied to all appropriate first line biological therapies.

If NICE approve the use of golimumab, it will provide an important further choice for patients and the professionals who treat us.

Yours sincerely