

F. No. CT/294/10-DCG (I)
Directorate General of Health Services
Office of Drugs Controller General (India)

FDA Bhawan New Delhi
Dated: **22 MAR 2011**

To,
M/s Wockhardt Ltd.
Wockhardt Towers, Bandra Kurla Complex,
Bandra (East), Mumbai-400 051

Subject: "A open label, randomized, comparison of the Immunogenicity and safety of Wockhardt's Human Insulin Basal Bolus Regimen (Intensified Conventional Insulin Therapy with Soluble Insulin and Isophane Insulin (Wosulin R, Wosulin N and Wosulin 70/30) with the Novo Nordisk's yeast based Human insulin Basal Bolus Regimens, marketed in United States (Novulin R, Novulin N and Novulin 70/30) in Type 1 Diabetes, Protocol No. P3-WOS-IMS-01, Version 05 Final, 22 Sep, 2010

Reference: Your letter No. Nil, dated 17.02.2011 (Dy. No. 8193, dated 21.02.2011)

Sir,

This Directorate has no objection to your conducting clinical trials with the said drug under the supervision of the investigators mentioned in your letter and as per the protocol forwarded to this Directorate. At the time of submitting clinical trials reports to this Directorate for evaluation you are required to comply with the following requirements:-

1. Submit complete report of clinical trials as per the approved protocol from the individual investigator duly signed by him along with his observations/remarks on the drug.
2. Indicating the date of commencement and conclusion of the clinical trial at each center (in case the study is multi-centric).
3. Approval of the Ethical Committee of the concerned centre/institution for conducting the clinical trial with the said drug.

You are requested to submit to this Directorate an annual status report on each clinical trial viz. ongoing, completed or terminated. In case the trial is terminated the reasons for the same should be communicated to this Directorate. In case any unexpected serious adverse reaction is observed during trial, the same should be immediately communicated.

It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not convey or imply that based on the clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.

You are also requested to follow Ethical aspects of the clinical trial as described in the booklet "Ethical Guidelines for Biomedical Research on Human Subjects" published by Indian Council of Medical Research (ICMR), New Delhi, and 'GCP' guideline issued by this Department and to obtain Ethical Committee clearance of the Institute before initiation of the study. Ethical Committee clearance should be obtained before initiation of the study.

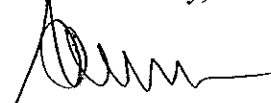
It is mandatory to register this clinical trial at ICMR clinical trial registry at www.ctri.in before enrolling first patient in the study.

In future correspondence, you may intimate this Directorate that you have registered the study as mentioned above.

In case of study related injury, you will provide complete medical care as well as compensation for the injury and statement to this effect should be incorporated in the Informed Consent Form.

You are also directed to enroll not more than 100 patients from India.

Yours faithfully,



(Dr. Surinder Singh)
Drugs Controller General (India)

File No. CT/286/10-DCG(I)
Directorate General of Health Services
Office of Drugs Controller General (India)

Dy. 53963, Dt. 18/11/2010

FDA Bhawan New Delhi
Dated:

21 MAR 2011

To,
M/s. Quintiles Research (India) Ltd.,
2B, Nitesh Broadway,
9/3, M.G. Road,
Banglore-560001.

Sub: "A phase II/III seamless, multi-center, randomized, double-blind, placebo-controlled study of the reduction in signs and symptom and inhibition of structural damage during treatment with tocilizumab versus placebo in patients with ankylosing spondylitis who have failed non-steroidal anti-inflammatory drugs and are native to TNF antagonist therapy:, protocol no. NA22823B, Dt. July 06, 2010-Reg.

Reference: - Your letter No. QR/RA/314/2010/02, dated 16/11/10.

Sir,

This Directorate has no objection to your conducting clinical trials with the said drug under the supervision of the investigators mentioned in your letter and as per the protocol forwarded to this Directorate. At the time of submitting clinical trials reports to this Directorate for evaluation you are required to comply with the following requirements:-

1. Submit complete report of clinical trials as per the approved protocol from the individual investigator duly signed by him along with his observations/remarks on the drug.
2. Indicating the date of commencement and conclusion of the clinical trial at each center (in case the study is multi-centric).
3. Approval of the Ethical Committee of the concerned centre/institution for conducting the clinical trial with the said drug.

You are requested to submit to this Directorate an annual status report on each clinical trial viz. ongoing, completed or terminated. In case the trial is terminated the reasons for the same should be communicated to this Directorate. In case any unexpected serious adverse reaction is observed during trial, the same should be immediately communicated.

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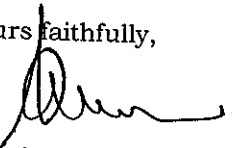
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In future correspondence, you may intimate this Directorate that you have registered the study as mentioned above.

In case of study-related injury, you will provide complete medical care as well as compensation for the injury and statement to this effect should be incorporated in the Information Consent Form.

You are directed to submit the data of the part 1 of the study and continue the part 2 of the clinical study only after satisfactory evaluation of the data and approval by this Directorate.

Yours faithfully,



(Dr. Surinder Singh)
Drugs Controller General (India)

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F. No. CT/232/10-DCG (I)
Directorate General of Health Services
Office of Drugs Controller General (India)

FDA Bhawan New Delhi
Dated: 21 MAR 2011

To,
M/s Quintiles Research (India) Private limited
2B, Nitesh Broadway, 9/3, M.G. Road,
Bangalore-560 001

Subject: "A Randomized, Double- Blind, Parallel group placebo controlled study of the safety & reduction of signs and symptoms during treatment with Tocilizumab (TCZ) versus placebo in patients with ankylosing spondylitis who have had an inadequate response to previous TNF antagonist therapy, Protocol No. WA22908B, dated 6 July, 2010

Reference: Your letter No. QR/RA/315/2011/02, dated 17 Jan, 2011

Sir,

This Directorate has no objection to your conducting clinical trials with the said drug under the supervision of the investigators mentioned in your letter and as per the protocol forwarded to this Directorate. At the time of submitting clinical trials reports to this Directorate for evaluation you are required to comply with the following requirements:-

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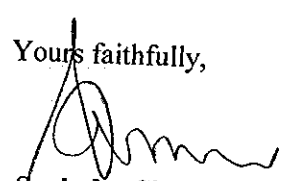
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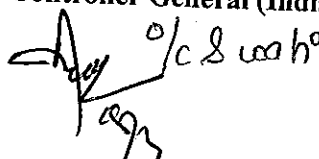
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Yours faithfully,


(Dr. Surinder Singh)
Drugs Controller General (India)


21 MAR 2011