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Clinical Research

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Tomas Salmonson
CHMP Chairman
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

17 January 2014

Subject: Withdrawal of Winfuran (Nalfurafine), 5 micrograms, concentrate for solution for infusion - EMEA/H/C/002683

Dear Tomas Salmonson

I would like to inform you that, at this point of time, Toray International U.K. Limited has taken the decision to withdraw the application for Conditional Marketing Authorisation of Winfuran (Nalfurafine), 5 micrograms, concentrate for solution for infusion, which was intended to be used for the treatment of severe uraemic pruritus (UP) in adults, with end stage renal disease undergoing regular haemodialysis, haemodiafiltration or haemofiltration (dialysis). Severe UP is defined as intolerable itching or itching unrelieved by scratching.

This withdrawal is based on the following reason:

- the CHMP considers that the data provided do not allow the committee to conclude on a positive benefit/risk balance

There are no on-going clinical trials with Nalfurafine being conducted, nor is there a compassionate use programme.

The Applicant intends to continue development of this product initially seeking Protocol Assistance from the CHMP to discuss the design of a Phase III study, which had previously been planned as a post-approval confirmatory study.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

Yours sincerely

[redacted]

[redacted]
Senior Director Regulatory Affairs
ICON Clinical Research
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Copies to:
Product Team Leader: [redacted]