Triskel EU Services Ltd

[redacted]

London 27 March 2017

European Medicines Agency
30 Churchill Place
Canary Wharf
London
E14 5EU
United Kingdom

Withdrawal of Solithromycin Triskel EU Services (solithromycin), 200 mg oral hard gelatin capsule and 400 mg Powder for concentrate for solution for infusion - EMEA/H/C/004179

Dear Dr. Salmonson,

I would like to inform you that, at this point of time, Cempra Pharmaceuticals Inc., which Triskel EU Services Ltd represents as the Applicant, has taken the decision to withdraw the application for Marketing Authorisation of Solithromycin Triskel EU Services, 200 mg oral hard gelatin capsule and 400 mg powder for concentrate for solution for infusion, which was intended to be used for the treatment of:

- community acquired pneumonia (CAP)
- inhaled anthrax
- inhaled tularaemia

Cempra Pharmaceuticals has taken this decision based on FDA's request to provide additional clinical safety data on solithromycin. Cempra currently plans to provide additional data to the FDA, and to include it upon resubmission of an MAA in the EU. We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

In addition to pursuing additional clinical safety data in adult pneumonia patients, Cempra also continues to evaluate solithromycin for the treatment of CAP in pediatric patients.

This decision will not have consequences for patients enrolled in any ongoing Cempra-sponsored solithromycin study at this time. There are no compassionate use programmes for solithromycin at this time and any such requests will be evaluated on a case-by-case basis.

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

Yours sincerely,

[redacted]

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