

CTI Life Sciences Limited



BioPark
Broadwater Road
Welwyn Garden City T +44 (0)1707
Hertfordshire AL7 358671
3AX F +44 (0)1707
United Kingdom 358672

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Dr. Abadie, CHMP Chair
European Medicines Agency
7, Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

**Subject: Withdrawal of OPAXIO™ (paclitaxel poliglumex) 269 mg Powder for Concentrate for Solution for Infusion
Marketing Authorisation Application Number: EMEA/H/C/994**

Dear Dr. Abadie,

I would like to inform you that CTI Life Sciences, Ltd. wishes to withdraw the application for the Marketing Authorisation of OPAXIO™ which was intended to be used as a first line monotherapy treatment of PS2 patients with advanced Non Small Cell Lung Cancer (NSCLC).

This withdrawal is based on the following:

- the EMEA's concerns whether a single agent chemotherapy regimen containing gemcitabine is an active controlarm for the treatment of NSCLC patients who have poor performance status
- the EMEA's concerns with the applicability of a non-inferiority test when the active control arm is in question
- the potential interim analysis in GOG-212 pivotal trial of maintenance OPAXIO™ therapy for Ovarian Cancer patients who achieve a CR following 1st line induction.

At this time, there is no on-going clinical trial in the EU with OPAXIO™. Similarly, no patient is currently treated with OPAXIO™ under compassionate use.

Currently in the US, Opaxio is under development:

- Ovarian -- A randomized phase 3 study of maintenance therapy comparing single agent Paclitaxel or Paclitaxel poliglumex vs. no treatment until documented relapse in women with advanced ovarian cancer who have a complete response to primary Platinum/Taxane chemotherapy.

- NSCLC -- A randomized, open-label, phase 3 study in Paclitaxel poliglumex/Carboplatin vs. Paclitaxel/Carboplatin for treatment of chemotherapy-naïve non-small cell lung cancer (NSCLC) in women with estradiol >25 pg/ml who are not candidates for combined modality therapy.
- Esophageal – A Phase 2 trial is concluding using OPAXIO in esophageal cancer. Following the conclusion of this study, CTI is also planning for development of a phase 3 multicenter randomized study evaluating neoadjuvant trimodality treatment comparing Opaxio, Cisplatin and radiation vs. 5-FU, Cisplatin and radiation for patients in locally advanced esophageal cancer.

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 EMEA website.