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14 Nimotuzumab Cuban Safety Postmarketing Surveillance

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Introduction: Nimotuzumab is a humanized monoclonal antibody against the human EGFR, it is been developed for use as monotherapy and in combination with radiation therapy and/or chemotherapy for the treatment of cancers of epithelial origin. Nimotuzumab is approved for marketing for the treatment of head and neck cancer and glioma in Argentina, Colombia, Cuba, China, Gabon, India, Ivory Coast, Peru and Ukraine.

Aims: A prospective postmarketing surveillance is been undertaken to assess safety of nimotuzumab as monotherapy and in combination with radiochemotherapy for the treatment of cancers of epithelial origin.

Methods: All patients receiving nimotuzumab outside clinical trials have been included in this study in thirty five Cuban hospitals. Patients were selected for the study if they met the following criteria: nimotuzumab medical prescription; confirmed cancer diagnosis; Life expectancy ≥3 months; ECOG 0-2; signed Informed Consent Form.

Nimotuzumab was delivered at the recommended dose, 200 mg/dose (adults) or 100 mg/m^2 dose (pediatrics) as weekly IV infusion, during 6 weeks, plus chemotherapy/radiotherapy as per standard of care. During the maintenance phase, nimotuzumab was administered at the same doses every 15 (pediatrics) or 21 days (adults), until progression of clinical deterioration.

Patient characteristics, drug delivery and safety of treatment were collected in individual Case Report Form, and then entered in a database. NCIC-CTC version 3.0 grading of adverse events was used to assess toxicity.

Results: Between July 2005 and January 2008, 425 patients, have been treated. Adult (age > 18 years; n=363) and children (age ≤ 18 years; n=62) represents eighty five and fifteen percentage respectively. The main tumor anatomic sites at baseline were: Head and Neck (n=160; 37.6%); Central Nervous System (n=129; 30.4%); Lung (n=68; 16%); Colorectal (n=16; 3.8%) and Cervix (n=10; 2.4). Nimotuzumab average doses received were 11 (from 1 to 58 doses) and the average exposition 7.9 months (min 0.7 months; max 30.60 months).

Treatment was well tolerated. Asthenia (2.8%), hypertension (2.1%), fever (1.6%), headache (1.6%), anorexia (1.4%), and vomits (1.4%), were the most frequently reported adverse events. Grade 1 mucositis and skin rash only occurred in 4 patients (0.01%). Grade 4 anaphylaxis was reported in one patient after the first dose, nimotuzumab was discontinued and the patient recovered. There was no treatment-related death.

Conclusion: Nimotuzumab is safe. A formal assessment of the benefit/risk ratio of nimotuzumab in the post approval indications will be carried out in prospective clinical trials in order to better define safety population profile.

Conflicts of interest: None declared.