IFCT-1001 CHIVA trial: A phase II study of carboplatin (Ca) plus pemetrexed (P) followed by maintenance P as first-line therapy for Human Immunodeficiency Virus positive (HIV+) infected patients (pts) with advanced non-squamous non-small cell lung cancer (NS-NSCLC).


BACKGROUND

The use of therapy in developed countries starting in 1993 has reduced in AIDS mortality due to opportunistic infections and AIDS-defining cancers. However, increased life expectancies were accompanied by a diversification of the causes of death in HIV-infected individuals. In 2010 cancer represented 34% of the causes of death in France and lung cancer was the first cause of mortality by cancer.

The prognosis of LC is worse in HIV-positive individuals. Some authors suggested that these poor outcomes may be related to interactions and additive toxicities of the cytotoxic and antiretroviral drugs. It is also likely that the disease is particularly aggressive. Recommendations for treatment of advanced NSCLC are lacking in this population, as HIV-related NSCLC is an exclusion criteria from most trials.

PATIENT CHARACTERISTICS

Four cycles of CaP were administered, followed by P until progression in controlled patients with PS ≥ 2 after induction.

METHODS

The primary endpoint was a ≥ 30% disease control rate (DCR) after 12 weeks.

Secondary endpoints were objective response rate, progression-free survival (PFS) and overall survival (OS), as well as the incidences of adverse events (AE) and opportunistic infections.

Statistical analysis: Fleming (1 step) alpha=0.05, beta=0.10 p0=30%, p1=50% ph=30%, ph1=50%, phh = p p-ph=10% versus H1: p ≥ p1

Alternate treatments: In case of progressive disease (PD), treatment may be interrupted or switched to a new one defined in a multidisciplinary meeting.

QUALITY OF LIFE (QoL)

OVERVIEW OF TOXICITIES (cycle 1 to 4)

CONCLUSIONS

1/ Four cycles of CaP induction, followed by P maintenance, were effective and reasonably well-tolerated in first-line therapy of HIV-infected patients with NS-NSCLC.

2/ Any opportunistic infection was observed.

3/ Overall survival was shorter than in general population whereas HIV-infected patients have a good immunovirological control. There is an urgent unmet need for investigation of other therapies, particularly immune-based therapies targeting the immune checkpoints.

No fatal event during the maintenance by pemetrexed.