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A biomarker for prognosis in lung cancer

Researcher from the Hospital del Mar Medical Research Institute have found a biomarker that is associated poor outcome in small cell lung cancer patients.

An offer for Patent Licensing and/or R+D collaboration

Prognosis of small-cell lung cancer (SCLC)

Small cell lung carcinoma (SCLC) is a highly lethal disease and accounts for approximately 15% of patients with lung cancers. This represents over 30000 new patients in the USA and 270000 cases in the world per year. Many genetic alterations have been identified with potential therapeutic interest. Outcome in advance stage remains poor with a median overall survival that does not exceed one year with available treatments (chemotherapy) that are not devoid of relevant toxicities.

This study has included **more than 100 patients** diagnosed of SCLC with complete clinical information and follow-up. Evaluation of **serial serum samples at different points** in time for each patient has shown that high levels of serum hepatocyte growth factor (sHGF) predict for a highly significant **shortened survival** (7months vs 14 months) and a 30% incremental risk for death for every increase in 1000 units of sHGF. Moreover, changes of serum levels of sHGF during treatment also predicted for outcome in this disease.

The researchers also evaluated the association of sHGF levels with the primary tumor in 45 cases. They found that higher sHGF levels are associated with Met activation features in the tumor. Therefore this marker obtained with a blood sample could substitute the performance of an invasive biopsy of the tumor and be predictor of benefit from **anti-Met therapies.**

Main advantages and applications

SCLC remains one of the neoplasms with less available efficacious treatments, leading to early death of the majority of patients. Many studies are being conducted with targeted therapies, however correlative biomarker

studies are still lacking in the majority of the cases. Any improvement for the patients with SCLC regarding diagnosis or treatment would cover a very urgent **unmet medical need**.

Many pharmaceutical companies are now developing HGF/Met inhibitors in clinical trials (phase1-3). However, some of these agents in phase 3 trials have failed to demonstrate benefit in other tumors (NSCLC) probably due to the lack of correct selection of patients for the drugs. This results in very **high personal costs** with patients failing to get benefit of new therapies and **very high economical costs** for the companies developing these agents; it is estimated that Life science companies spend, on average, $56.3 million and eight years to advance an oncology product from Phase 1 through Phase 3. These costs could be substantially reduced identifying early in the process a robust and easily applicable predictive biomarker of response to a specific therapy.

Here the investigators propose a **non-invasive method** that provides information about the prognosis of the patient and about the Met activation status of the tumor.

This biomarker could be useful to **select patients for clinical trials of Met inhibitors** in SCLC and potentially in other tumors as a **companion diagnostic test** for regulatory approvals if the trials succeed.

This test could be used as an exploratory diagnostic test in clinical trials with Met inhibitors. If these trials are positive and get to approval, the test should be initially performed in all patients with SCLC, providing a **large market of patients** for the use of the test.

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