

Immuno and targeted therapy provide new options for difficult-to-treat head and neck cancer

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Novel strategies are on the way for difficult-to-treat and advanced head and neck cancer, the most heterogeneous group of malignancies which are generally associated with poor survival, and encouraging results have been presented at the first ESMO Asia 2015 Congress in Singapore.

In a Phase I trial (1), the immunotherapy agent pembrolizumab has shown promising antineoplastic activity in [patients](#) with heavily pretreated nasopharyngeal cancer, who currently have no effective treatment options. In a large Phase II trial, the targeted agent afatinib was effective in the second-line treatment of recurrent or metastatic squamous cell carcinoma (HNSCC) after failure with platinum-based therapy.

Incidence of some types of head and [neck cancer](#) varies substantially between Asia and Europe, to some extent limiting novel options for patients. ESMO spokesperson Dr. Lisa Licitra, chief of the Head and Neck Cancer Medical Oncology Department and head and neck research programme at the Istituto Nazionale Tumori in Milan, Italy, explains this epidemiological difference. "It clearly points out that risk factors for disease development may vary across countries thus potentially affecting the disease biology. To date these biological differences have not been studied and in this sense research may be affected in terms of generalisability of results," she said.

Nasopharyngeal cancer (NPC) is endemic in Asia, with a high incidence in some areas of the continent (26.9 per 100,000 in Southern China), where it is mostly associated with Epstein-Barr virus (EBV) infection. While this type of cancer is rare in Europe and US, in Asian countries it represents a major health issue. KEYNOTE-028 is a non-randomised, multicohort, Phase Ib trial which assessed the safety, tolerability and preliminary efficacy of pembrolizumab in patients with PD-L1 positive advanced solid tumours, including 27 patients with nasopharyngeal cancer. "This study provides the first demonstration of clinical activity of a PD-1 inhibitor in 27 patients with recurrent/metastatic NPC, with an objective response rate of 22.2%," says study author Professor Chiun Hsu, Department of Oncology, National Taiwan University Hospital, Taipei, Taiwan. "We observed a median duration of response of 10.8 months. Pembrolizumab showed a manageable safety profile". Patients were heavily pretreated, including 7 patients who had received at least 5 prior lines of systemic treatment.

"Immunotherapy is a very promising strategy for head and neck cancer and we are awaiting the results of pivotal studies in second-line treatment for recurrent and metastatic patients," Licitra said. "To date we only have promising response rate and PFS data from non-comparative studies. For nasopharyngeal cancer a Phase III study is still to be developed. The development of these drugs in second line might obscure the real impact of these drugs in the disease as patients at advanced stage are highly immunocompromised irrespective of the previous treatment they have received."

Although squamous cell carcinoma of the head and neck is the most common type of cancer in this group, currently it also has a very poor prognosis with no well-defined standard of care after the failure of previous platinum-based therapy. The ErbB family of receptors (including EGFR, HER2, HER3 and HER4) plays an important role in tumourigenesis, and EGFR overexpression (occurring in ~90% of

HNSCC cases) is associated with poor prognosis in HNSCC.

The first results from the randomised, open-label, Phase III LUX-Head & Neck 1 trial (2) were presented earlier this year and showed that afatinib, an oral irreversible ErbB family blocker, significantly delayed tumour growth versus chemotherapy in patients following failure of their previous treatment, reducing the risk for disease progression by 20%.

Commenting on the efficacy outcomes in selected pre-specified subgroups and biomarker-defined populations, first author Dr. Makoto Tahara, Department of Head and Neck Medical Oncology, National Cancer Center Hospital East, Kashiwa, Japan, says: "The PFS benefit observed with afatinib over methotrexate was generally consistent across most pre-specified patient subgroups analysed, including subgroups based on geographical region (Asia, Europe, or North/Latin America). The ErbB family blocker showed benefit over methotrexate regardless of patient age (>65 or

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