PRESS RELEASE

Breakthrough in Hypoxic Modification for Head and Neck Cancer Patients receiving Chemoradiation Treatment Presented at ESTRO 2025

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Clinical Study Demonstrates Improved Locoregional Control with Nimorazole in Advanced Head and Neck Cancer

A recent multicenter randomized trial presented at the European Society for Radiotherapy and Oncology (ESTRO) 2025 conference has revealed significantly positive results for the use of AFYX Therapeutics A/S patented proprietary nimorazole (NIM) product as a hypoxic radiosensitizer in the treatment of locally advanced HPV-negative head and neck squamous cell carcinoma (HNSCC). The study, led by Vincent Gregoire, Jens Overgaard and colleagues from various European institutions, aimed to confirm the benefits of NIM in combination with accelerated chemo-radiotherapy.

Key Findings:

- Study Design: The trial included 194 patients with stage III-IV laryngeal, hypopharyngeal, or HPV-negative oropharyngeal SCC, randomized to receive either NIM or placebo alongside chemo-radiotherapy.
- Treatment Regimen: Accelerated radiotherapy was delivered using IMRT (70 Gy in 6 weeks), with cisplatin administered either weekly (40 mg/m²) or every three weeks (100 mg/m²). NIM or placebo was given orally at a daily dose of 1.2 mg/m² prior to each fraction of radiation.

- Primary Endpoint: The primary endpoint was the 3-year locoregional failure rate. Results showed a significant (p-value 0.04) reduction in locoregional failure for patients receiving NIM (18%) compared to placebo (30%), with a hazard ratio (HR) of 0.63.
- Secondary Endpoints: Disease-specific survival (DSS) and overall survival (OS) did not show significant differences between the NIM and placebo groups.
- Safety and Compliance: Treatment compliance was similar across both groups, with no significant differences in treatment-related morbidity except for higher nephrotoxicity in the 3-weekly cisplatin regimen.

Conclusion: Despite the reduced patient number due to premature trial closure, the study demonstrated that nimorazole improves locoregional control in advanced HPV-negative HNSCC. This underlines that hypoxic modification is still active in concomitant chemo-radiotherapy of squamous cell carcinoma.

At AFYX, "Reversed Innovation" is our core value. As a leader in the biopharmaceutical industry, we focus on repurposing existing products or technologies to address new or previously overlooked medical conditions.

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