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Dear ALL

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Publication of Phase II Clinical Trial Results for DFP-14323 in Combination with Low-Dose Afatinib in Therapeutic Advances in Medical Oncology

Peer-reviewed publication provides further clinical evidence for a novel treatment approach for EGFR mutation-positive non-small cell lung cancer

We are pleased to announce that the results of the Phase II clinical trial evaluating **DFP-14323 (generic name: ubenimex)** in combination with low-dose afatinib in patients with **EGFR mutation-positive non-small cell lung cancer (NSCLC)** have been published in the international peer-reviewed journal *Therapeutic Advances in Medical Oncology*.

The clinical trial results had previously been presented at scientific meetings and publicly disclosed. The publication represents the formal peer-reviewed reporting of these clinical findings in an international medical journal.

Overview of the Phase II Clinical Trial

The Phase II trial evaluated the efficacy and safety of the combination of DFP-14323 at 10 mg/day and low-dose afatinib as first-line treatment for patients with advanced or recurrent NSCLC harboring common EGFR mutations, including **Exon 19 deletion and L858R**.

A total of 26 patients were enrolled in this multicenter, prospective, open-label, single-arm Phase II study.

The **disease control rate (DCR) was 100%**, while the **objective response rate (ORR) was 69.2%**. The median **progression-free survival (PFS) was 23.1 months** with extended follow-up.

The safety profile was also favorable. No Grade 4 or 5 treatment-related adverse events or treatment-related deaths were reported. Although treatment interruptions due to afatinib-related diarrhea or skin disorders occurred in some patients, **no patients discontinued treatment because of adverse events**.

A Novel Therapeutic Approach Combining Targeted Therapy and Immunomodulation

DFP-14323 is an **immunomodulatory agent targeting CD13 (aminopeptidase N)**. Afatinib directly inhibits tumor cell proliferation through EGFR signaling blockade, while DFP-14323 is designed to modulate the tumor microenvironment and immune-suppressive mechanisms. The combination therefore represents a therapeutic strategy integrating **direct antitumor activity with immunomodulation**.

The clinical findings suggest the potential of combining DFP-14323 with low-dose EGFR tyrosine kinase inhibitor (EGFR-TKI) therapy. However, because this Phase II study was a single-arm study without a control group, the contribution of DFP-14323 to the observed clinical outcomes cannot be definitively established from this study alone. Further clinical investigation is therefore warranted.

Significance of the Publication

The publication of these results in a peer-reviewed international medical journal provides an important opportunity to share the clinical data on DFP-14323 with the global oncology community.

We believe that the publication further supports the scientific and clinical rationale for investigating DFP-14323 as an immunomodulatory component of combination cancer therapy and contributes to the continued development of this novel therapeutic approach.

Outlook

Based on the clinical findings from the Phase II study, further clinical development of DFP-14323 in combination with EGFR-targeted therapy is being pursued.

We remain committed to advancing the clinical development of DFP-14323 and to exploring its potential as a novel therapeutic approach that combines **targeted anticancer therapy and modulation of the tumor microenvironment**.

Publication Details

Title:
A phase II study of DFP-14323, a non-specific immunomodulator, in combination with low-dose afatinib as first-line therapy for common EGFR mutation-positive NSCLC
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