ORIENT-12 Study demonstrates adding sintilimab to gemcitabine/platinum has clinical benefit

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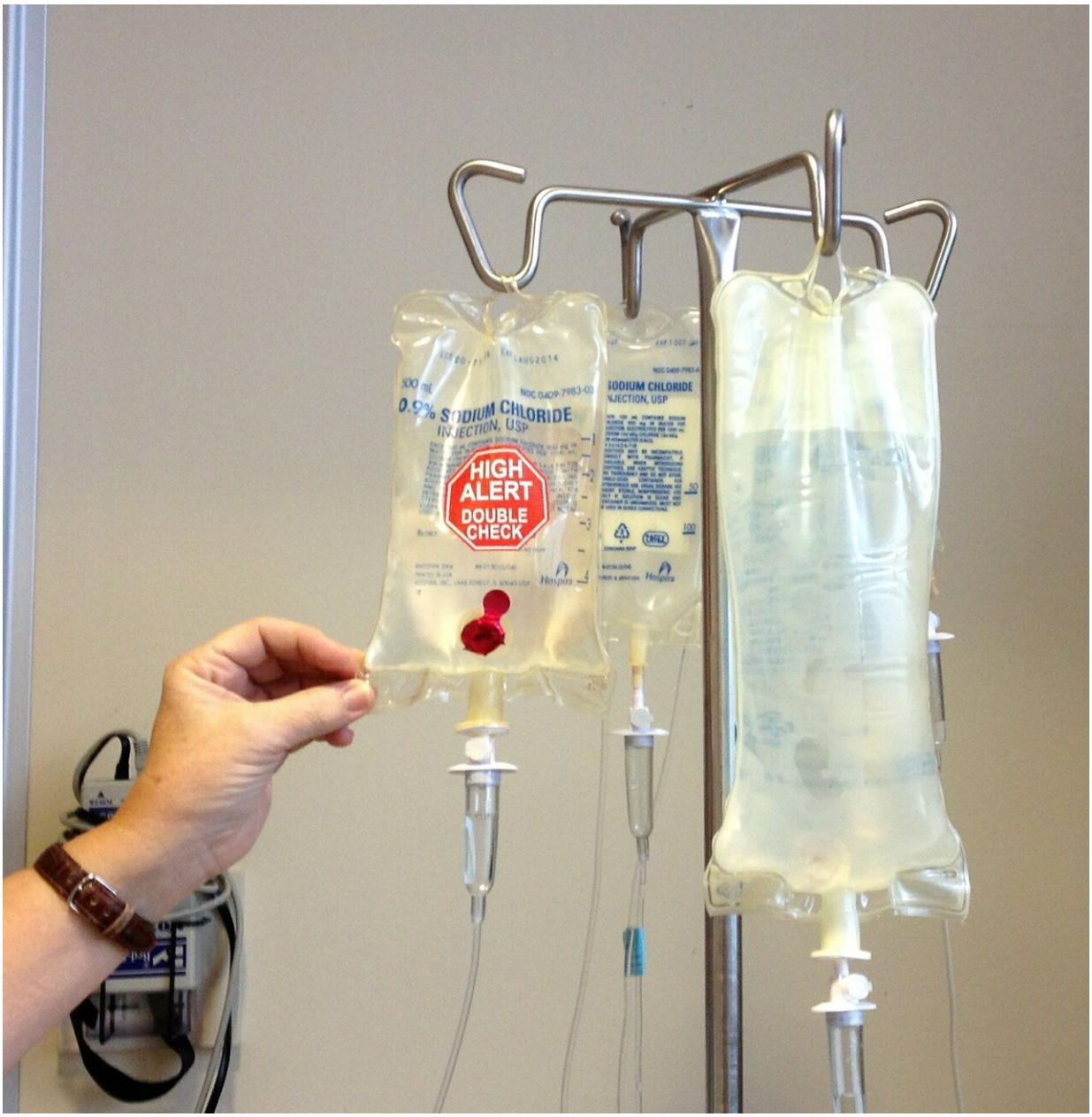

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Adding sintilimab to a regimen of gemcitabine and platinum demonstrates clinical benefit over gemcitabine and platinum alone as first-line therapy in patients with locally advanced or metastatic

squamous cell non-small cell lung cancer, according to a study published in the *Journal of Thoracic Oncology*, the official journal of the International Association for the Study of Lung Cancer.

The standard chemotherapy for squamous NSCLC (sqNSCLC), includes platinum plus gemcitabine. sintilimab, an anti-PD-1 antibody, plus platinum/gemcitabine, has shown encouraging efficacy as first-line therapy for sqNSCLC in the phase III study ECOG 1594. Platinum/gemcitabine is another standard regimen of chemotherapy for sqNSCLC and is commonly used in Asia.

Led by Caicun Zhou, MD, Ph.D., from Shanghai Pulmonary Hospital in Shanghai, China, the researchers conducted a randomized, double-blind, phase 3 study to further compare the efficacy and safety of sintilimab with placebo, both in combination with gemcitabine/platinum.

Dr. Zhou and his co-researchers randomized patients with locally advanced or metastatic sqNSCLC and without EGFR-sensitive mutations or ALK rearrangements. Overall, researchers screened 543 patients from 42 centers throughout China. Of those, 357 patients were randomized into the sintilimab-gemcitabine/platinum group (n=179) and the placebo-gemcitabine/platinum group (n=178).

The primary endpoint was progression-free survival (defined as the time from randomization to the first disease progression or death from any cause), as assessed by the independent radiographic review committee.

After a median follow-up period of 12.9 months, patients in the sintilimab-gemcitabine/platinum group continued to demonstrate a meaningful improvement in progression-free survival over the placebo-gemcitabine/platinum group (HR 0.536 [95% CI 0.422-0.681]; p

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