Noile-Immune Biotech

News Release

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https://www.noile-immune.com

Noile-Immune Biotech's Position on Secondary Tumor Risk in CAR-T Cell Therapy

Noile-Immune Biotech, Inc. (hereinafter referred to as 'Noile-Immune') here describes company position on the announcements by the U.S. Food and Drug Administration (hereinafter referred to as 'FDA') investigating risks of T-cell malignancies following treatment with autologous CAR-T cell therapies targeting BCMA and CD19, in order to address some inquiries given by stakeholders.

Summary of the FDA Announcement:

On November 28, 2023 (U.S. local time), the FDA announced that it has received reports of adverse events related to T-cell malignancies in patients who had received CAR-T cell therapy targeting CD19 or BCMA, both in clinical trials and post-commercialization. The FDA stated that although the overall benefits derived from these products continue to outweigh the potential risks, they are initiating an investigation into the risks associated with T-cell malignancies with serious outcomes, including hospitalization and death. They are also evaluating the need for regulatory action.
https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-investigating-serious-risk-t-cell-malignancy-following-bcma-directed-or-cd19-directed-autologous

Our Position:

Some anti-tumor drugs and radiation therapy, though with the low probability, have a risk of causing secondary tumors. For example, certain types of anti-tumor drugs have a risk of inducing hematologic malignancies such as leukemia and myelodysplastic syndromes, while radiation therapy does in organs within the irradiated area. However, the benefits cancer patients receive from these treatments are generally believed to outweigh the risks of secondary tumors, therefore they are utilized as part of standard treatments. Similarly, CAR-T cell therapies can be considered as one of meaningful treatment approaches, if the treatment benefits outweigh a risk of inducing T-cell malignancies.

Noile-Immune is committed in research and development of next-generation CAR-T cell therapies implementing our original PRIME technology, aiming at providing patients with safe and effective treatment for advanced solid tumors that are difficult to treat with current standard therapies. Similar to the FDA's comments on the current CAR-T cell therapies for blood cancers, Noile-Immune considers that the benefits patients receive from our next-generation PRIME CAR-T cell therapies should outweigh its potential risks. Noile-Immune will closely monitor future updates from the FDA, actively pursue the development of our pipeline, and carefully monitor the safety, including the risk of secondary tumors. We are committed to delivering new treatments to cancer patients, their families, and healthcare professionals as soon as possible.

Noile-Immune Biotech Inc., established as a university start-up, aims to contribute to the arrival of an era when we can overcome cancer through the next-generation cancer immunotherapies, centering on PRIME technology.

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