FDA Grants Fast Track Designation for SNB-101 to Treat Small Cell Lung Cancer

SNB-101 is the first nanoparticle anticancer drug that was developed exceedingly insoluble SN-38 into polymer nanoparticles.

The FDA has granted fast track designation for a polymer nanoparticle anticancer drug, SNB-101 (API: SN-38), to treat individuals with small cell lung cancer (SCLC). The study authors noted that SNB-101 was designated as an orphan drug for SCLC and pancreatic cancer in July of 2023 and February of 2024, respectively. Additionally, SNB-101 is the first nanoparticle anticancer drug to be developed and is composed of extremely insoluble SN-38 incorporated into polymer nanoparticles, according to study authors.[1]

SCLC is an aggressive form of lung cancer that is recurrent and results in rapid progression, despite treatment efforts with chemotherapy and radiotherapy. Researchers noted that one-fifth of cancer deaths are cases of lung cancer and 15% of those cases are individuals with SCLC.[2]

The American Cancer Society has noted that small cell and non-small cell lung cancer are the second most common cancer in both men and women in the US, with an estimated 234,580 new cases and 125,070 deaths from lung cancer in 2024. Older adults aged 65 and older are more commonly diagnosed with lung cancer, compared with individuals younger than age 45.[3]

There is an unmet medical need following a SCLC diagnosis, despite extensive research, according to study authors. The current first line of treatment for individuals with SCLC is combination therapy with cisplatin and etoposide. The second line of treatment includes a cytotoxic anticancer drug and clinical trials.[1]

SN-38, which is used in the development of SNB-101, is an active metabolite of irinotecan that is used in antibody drug conjugates (ADCs). Researchers evaluated the tolerability and safety of SN-38 and found it displayed significant improvements compared with current treatment options, providing additional treatment options for lung cancer, pancreatic cancer, and gastric cancer.[1]

The fast track designation was granted based on preclinical and phase 1 clinical trial results which showed a reduction in digestive system adverse events with SN-101, compared to existing anticancer drugs. The reduced adverse effects included nausea, vomiting, and diarrhea. Additionally, the results showed admirable efficacy in individuals related to lung cancer through lung targeting, according to study authors.[1]

“Scale-up production, the biggest barrier that prevented existing nano-cancer drugs from entering the clinical stage, was successful, and clinical trial products are produced

at a facility dedicated to anticancer drugs with EU GMP," said study authors, in a press release.[1]

However, the study authors noted that approval for a phase 2 trial is being assessed in the U.S and Europe and global clinical trials are scheduled to begin following the approval. The phase 2 clinical trials are aimed to expand indications of small cell lung cancer and pancreatic cancer for other solid cancers.[1]

References

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