# FDA Approves Sacituzumab Govitecan for Triple-Negative Breast Cancer

On April 22, 2020, the FDA has granted an accelerated approval to the antibody-drug conjugate (ADC) sacituzumab govitecan-hziy (Trodelvy, Immunomedics, Inc.) for the treatment of adult patients with metastatic triple-negative breast cancer (TNBC) who have received at least 2 prior therapies for metastatic disease. This is the first antibody conjugated drug targeting against TROP-2 that has received FDA approval to treat metastatic TNBC.

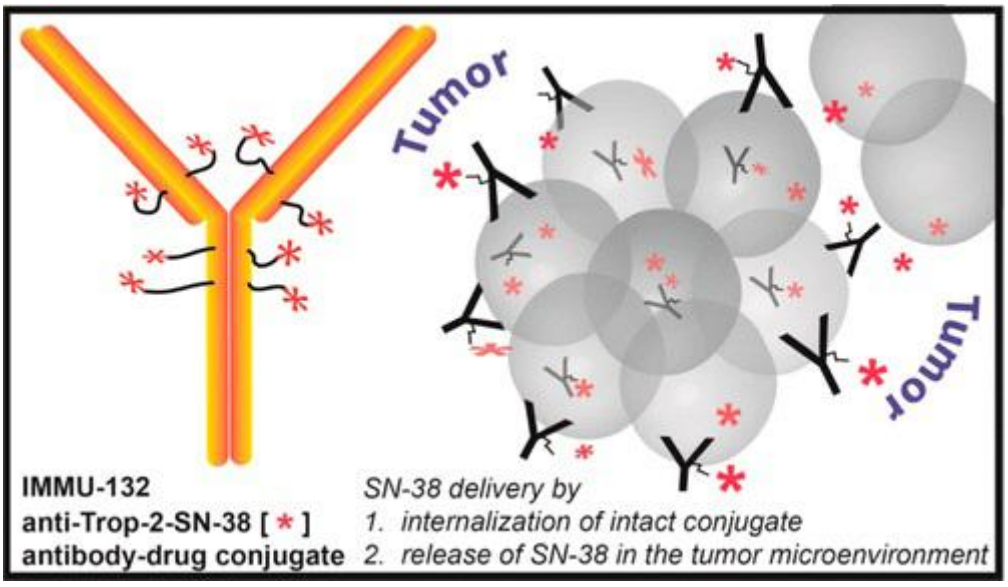


Image Source: https://pubs.acs.org/

Trop2 is a cell surface protein expressed in many solid tumors, which makes Trodelvy® potentially treat a variety of cancers. Trodelvy®'s cytotoxic small molecule drug is irinotecan's active metabolite SN-38 molecule, using Immunomedics' unique ADC platform. Trodelvy® combines with Trop2 and provides the anticancer drug SN-38 to kill cancer cells. Trodelvy® is currently undergoing clinical evaluation to treat 8 refractory solid tumors.

The FDA's approval is based on the results of a single-arm clinical phase II trial involving 108 patients with metastatic TNBC. Trodelvy demonstrated an ORR

of 33.3 percent (95 percent CI: 24.6, 43.1) and a median DoR of 7.7 months (95 percent CI: 4.9, 10.8). Of the patients with a response to Trodelvy, 55.6% maintained their response for 6 or more months and 16.7% maintained their response for 12 or more months.

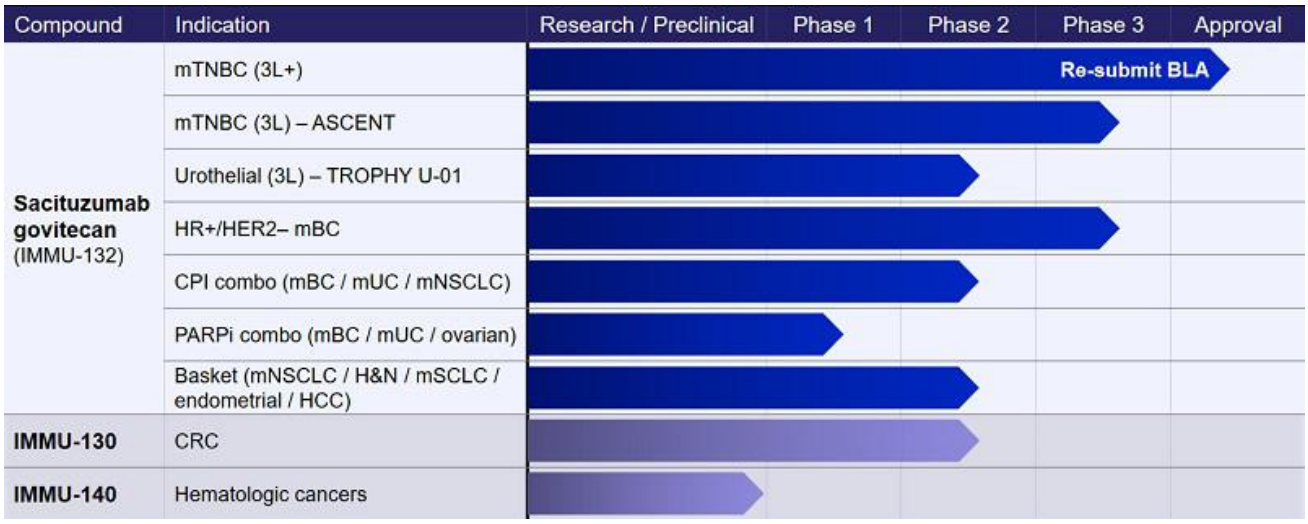


Image source: Immunomedics

## About TNBC & Therapies

Breast cancer is the most common type of cancer in women, with more than 2 million cases diagnosed worldwide each year. Three-negative breast cancer (TNBC) accounts for about 20% of all breast cancers. Compared with other types of breast cancer, TNBC is more common in women under 50 years of age. TNBC refers to breast cancer with negative expression of estrogen receptor (ER), progesterone receptor (PR) and HER-2 / neu. It progresses rapidly, with a very poor prognosis, and the 5-year survival rate is less than 15%. TNBC is ineffective for hormone therapy and HER2 targeted therapy (such as Herceptin of Roche). Clinical treatment options are very limited and mainly rely on chemotherapy.

Currently, there are 21 triple-negative breast cancer treatment drugs, 2 of which are on the market and 19 are in research. The first triple-negative breast cancer drug on the market was Roche's Atezolizumab, which was initially marketed in the United States in 2016. In 2019, global sales reached 1.932 billion US dollars.

There are 4 types of triple-negative breast cancer drugs in clinical phase II, 5 types in clinical phase I / II, and 7 types in clinical phase I. It can be said that

the reserve power is sufficient, but the R & D progress is relatively slow.

## Drugs Targeting Trop2

At present, there are five drugs targeting Trop2 in the world. In addition to the listed Sacituzumab govitecan, the other four drugs under study are basically in clinical phase I. The fastest R & D progress is SKB-264 of Kelun Pharmaceutical, which is currently in the clinical I / II phase of solid tumor treatment.

| Drug | Indications | Maker | Progress |
|---|---|---|---|
| Sacituzumab Govitecan | TNBC | Immunomedics | FDA Approved |
| SKB-264 | Solid tumor | Kelun Pharmaceutical | Clinical phase I / II |
| BAT-8003 | Gastric cancer<br>Breast cancer | Bio-Thera Solutions | Clinical phase I |
| DS-1062 | Non-small-cell lung cancer | Daiichi Sankyo | Clinical phase I |
| DAC-002 | TNBC<br>Small cell lung cancer<br>Non-small-cell lung cancer<br>Pancreatic cancer | Hangzhou DAC Biotech | IND |

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