Zefei Jiang: when ideals illuminate reality, more breast cancer patients will benefit from the inclusion of T-DM1 in China's national medical insurance catalog

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Editor's note

Antibody-drug conjugates (ADCs), known as "magic bullets", have brought a new era of anti-tumor treatment, especially in the systemic treatment of breast cancer. Trastuzumab emtansine (T-DM1) is globally the first approved ADC for the treatment of solid tumors and also the first ADC marketed in China, used as an adjuvant therapy for early breast cancer or as a second-line therapy for advanced tumors. After two indications of T-DM1 were covered by China's new national medical insurance catalog, T-DM1 has become much more accessible and affordable. Many breast cancer patients will benefit from this life-saving drug with more acceptable cost. How do ADCs fill up the gap between "ideal" and "reality"? How will them shape the landscape of breast cancer treatment? And, what treatment benefits will they bring to breast cancer patients? Focusing on these questions, Professor Zefei Jiang (*Figure 1*) from the Department of Oncology of Chinese PLA General Hospital shared his insights in an interview with *Oncology Frontier*.

Figure 1 Prof. Zefei Jiang, MD.

Oncology Frontier*: *The concept of "magic bullet" appeared more than 100 years ago. However, ADCs began to emerge in the 21st century. Have ADCs shaped the treatment landscape for early and advanced HER2-positive breast cancers in the past years?

Prof. Jiang: From the perspective of drug research and development (R&D), it was 100 years ago that it was hoped that cytotoxic drugs could be accurately brought into tumor tissues and cells. However, it was technically highly challenging to realize this idea. A blood product had been marketed but was then retracted due to toxicity problems; later, it was re-marketed after structural modifications.

T-DM1 is the first ADC for breast cancer. Many years ago, its clinical trials were registered and conducted in China, and I served as the PI of these trials. After it was licensed, it can be used in patients with advanced breast cancer, bringing breast cancer treatment from single-target, dual-target, and TKI therapies to the ADC era. As seen in many international trials, early breast cancer patients who have not achieved pathological complete response (non-pCR) can benefit more from intensified T-DM1 adjuvant therapy; meanwhile, T-DM1 also has a role in the second-line treatment of advanced breast cancer. We are

very pleased to witness the transition of such a precision treatment from ideal to reality and from bench to bedside; more importantly, its role has been officially recognized by China's clinical guidelines and regulatory authorities. Its increasing use in clinical settings will bringing more treatment benefits to more patients.

Oncology Frontier*: *A variety of therapeutic drugs such as large-molecule monoclonal antibody, small-molecule tyrosine kinase inhibitors (TKIs), and ADCs have been available in the treatment of HER2-positive advanced breast cancer. Could you please share with us the treatment strategies for HER2-positive advanced breast cancer?

Prof. Jiang: There was no drug for HER2-positive breast cancer in China 20 years ago. Trastuzumab has become a mainstay in the treatment of this malignancy in the past 10 years. On this basis, pertuzumab and TKIs have gradually been designed and developed. ADC treatment occurs in recent years. Actually we are writing a book on the 20-year history of anti-HER2 therapy, which comprehensively summarizes the treatment journey from single target to dual targets and from TKIs to ADCs.

At present, the treatments of advanced breast cancer need to be further classified. The anti-HER2 therapy is a large class of medicines targeting multiple mechanisms. In clinical practice, patients need to be stratified according to the response to trastuzumab treatment and previous anti-HER2 regimens. Trastuzumab-sensitive populations should be treated with a dual-target therapy (trastuzumab and pertuzumab) in combination with chemotherapy (e.g., taxanes). For patients who are not sensitive to trastuzumab treatment, TKIs or ADCs can be used instead, as recommended in the CSCO-BC guidelines. Accurate classification and precise stratification will further facilitate the development of more rational and economical treatment protocols and bring long-term benefits to patients with advanced diseases.

Oncology Frontier*: *This year's medical insurance negotiations have ended and the new national medical insurance catalog is urgently expected. Will the expansion of the health insurance catalog lead to change in breast cancer treatment and research in the coming years?

Prof. Jiang: China's medical insurance policy is undoubtedly a good policy for the benefits of the country and the people. Maybe it puts pressure on enterprises, but we all hope to treat more patients with the same budget. "Cheap and cheerful" is always pursued by consumers (i.e., patients and their families), although it can be very difficult in some situations. Medical insurance negotiations enable pharmaceutical companies to enter the market early. With larger market shares, they are able to supply more affordable and accessible drugs to more patients. Drugs in the early stage of marketing are really expensive and most patients can not afford them. Some patients may manage to receive 2–3 courses of treatment, they are difficult to afford subsequent treatments due to high out-of-pocket costs.

We had expected that trastuzumab, pertuzumab, and T-DM1, a new ADC, would be included in the national medical insurance catalog so that their prices could be lowered to reasonable and affordable levels. Nowadays our expectations have become a reality, and T-DM1 also fills up a gap in the second-line treatment of advanced breast cancer in the catalog. I hope more products will be covered by the national medical insurance, which will be conducive to the continuous care and all-line treatment of breast cancer. For clinicians, they can make more reasonable treatment decisions with more treatment options available at different stages of the disease; for patients, they have more equitable access to healthcare services.

Oncology Frontier*: *As the first and only ADC included in the national medical insurance catalog for the treatment of breast cancer, what benefits can Kadcyla® (T-DM1) bring to breast cancer patients?

Prof. Jiang: The clinical performance of Kadcyla® has long been recognized, and its inclusion in the national medical insurance catalog has long been expected. The high pricing strategy of Kadcyla® is understandable due to its high levels of R&D expenses. Fortunately, thanks to the mechanism of national medical insurance negotiations in China, the price of Kadcyla® finally fell to a more reasonable level and more patients can benefit from it. In particular, for high-risk patients with an early-stage breast (such as non-pCR patients), there is an opportunity to use T-DM1 in the adjuvant setting to reduce the risk of recurrence; for patients experiencing recurrence/metastasis (progression after trastuzumab/pertuzumab treatment or after pyrotinib treatment), T-DM1 can be used as a subsequent treatment, especially when another TKI has basically withdrawn from Chinese market.

In fact, the overall survival of HER2-positive advanced breast cancer patients has increased from 3–5 months

two or three decades ago to 3–5 years or even 7–8 years nowadays. During the treatment of advanced breast cancer, there is always a chance to prolong survival. Of course, as the price of T-DM1 becomes more reasonable after the drug is covered by the national medical insurance, more patients will be able to use it in time. Of course, more ADCs can be expected in the future. Competition is a good thing, and scientific ideas will make these ADCs available and affordable to more patients at reasonable prices. When new problems arise, we will adopt new drugs and methods to solve them. According to an old saying, "there are always more solutions than difficulties".

With the availability of new therapies, we hope HER2-positive breast cancer patients can be cured through neoadjuvant and adjuvant therapies in the early stages and have longer survival time in the advanced stages. Some patients in our hospital whose diseases had relapsed and metastasized 8 or 9 years before. They continued to receive the anti-HER2 therapies, from single-target to dual-target therapies and then to a series of treatments including TKIs and ADCs. Today their diseases are well controlled, and the patients enjoy a good quality of life. In summary, we hope the inclusion of T-DM1 in the national medical insurance catalog will help more breast cancer patients live longer and live better.

Expert introduction

Prof. Zefei Jiang. Deputy Director, Department of Oncology, Chinese PLA General Hospital, Vice Chairman of Beijing Medical Association Breast Diseases Branch, Vice President and Secretary-General of Chinese Society of Clinical Oncology (CSCO), Elected Chairman of the Professional Committee on Breast Cancer, China Anti-Cancer Association (CACA), Former Chairman of the Professional Committee on Breast Cancer, CSCO.

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Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

