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novel Chinese therapy is offering hope for patients with colorectal cancer in the United States.

Fruzaqla (fruquintinib), developed by Shanghai-based biopharmaceutical firm HUTCHMED, gained approval from the US Food and Drug Administration on November 8 as an oral targeted therapy for adults with metastatic colorectal cancer who have been treated with chemotherapy, anti-VEGF therapy and anti-EGFR therapy.

Just in 48 hours after its market launch in the US, the first prescription was released, making it the first Shanghai-developed innovative drug to be prescribed in the US, Shanghai Daily learnt from HUTCHMED.

Global biopharmaceutical leader Takeda helped with its global approval.

Fruquintinib is the first novel chemotherapy-free treatment option approved for patients in the US regardless of biomarker status in more than a decade, according to Teresa Bitetti, president of the global oncology business unit at Takeda.

"For far too long, health-care providers and patients have had limited options when selecting a therapy for metastatic colorectal cancer," she said, noting that it has the potential to offer a significant survival benefit

to patients without negatively impacting their quality of life.

According to the World Health Organization, colorectal cancer is the third-most common cancer world-wide, accounting for approximately 10 percent of all cancer cases and is the second leading cause of cancer-related deaths worldwide.

In 2020, more than 1.9 million new cases of colorectal cancer, with over 930,000 deaths, were estimated to have occurred worldwide. The number is expected to rise to 3.2 million and 1.6 million, respectively, in 2024.

Chinese patients account for nearly a third of the world's total. Nearly 10 percent of patients are in the US. Europe and Japan have also witnessed a high occurrence of colorectal cancer.

Colorectal cancer is often diagnosed at advanced stages when treatment options are limited. So, about 70 percent of patients end up suffering cancer metastasis after diagnosis and treatment.

Worse, for those with distant metastasis, their five-year survival rate is usually merely 14 percent, according to Su Weiguo, chief executive officer of HUTCHMED.

Facing limited options and poor outcomes, there was a pressing need for a more effective treatment. Fruquintinib has come to the rescue, Su said, noting that it was the first and only

selective inhibitor of all three VEGF receptor kinases approved in the US.

He added that fruquintinib can also be used together with other medicines to curb tumors in multiple ways.

Fruquintinib was released in China in 2018, after 12 years of research and development in Shanghai's biomedical industry highland of Zhangjiang. So far, it has benefited more than 60,000 Chinese patients.

According to HUTCHMED, the marketing authorization application of fruquintinib has been accepted by Europe for regulatory review, and its application to be launched in Japan has been submitted. So, it's expected to benefit patients in more countries and regions next year.

According to a survey by Boston Consulting Group, the US ranked first in sales of innovative medicines globally in 2021, with a market share of 55 percent. Five European countries — the United Kingdom, France, Germany, Italy and Spain — accounted for 16 percent, Japan and South Korea had 8 percent while China accounted for 3 percent.

Continuous medical reforms are pushing Chinese biopharmaceutical firms to develop innovative drugs and have a finger in the pie in the global landscape.

One of the most effective methods is marketing authorization holder. The program was designed

to segregate R&D and production, allowing medical device innovators to enable contract manufacturers to build samples and products, which was banned previously.

Shanghai's Pudong New Area pioneered the program in July 2016, and fruquintinib was one of the first fruits

So far, HUTCHMED has promoted global clinical trials of 13 self-developed anti-tumor candidates. Currently, it is working with Astra-Zeneca to develop the global approval of savolitinib as a novel therapy to treat lung and gastric cancers.

As for overseas approval, like HUTCHMED, most domestic biopharmaceutical companies have turned to work with global industry leaders.

Last month, another Zhangjiang-based firm Junshi Biosciences and its US partner Coherus BioSciences gained approval from the US FDA for the market launch of Loqtorzi (toripalimab-tpzi) for the treatment of adults with advanced metastatic nasopharyngeal carcinoma.

It is the first US FDA-approved agent for nasopharyngeal carcinoma patients.

Since 2008 when China launched the "major innovative drug" campaign, 80 first-in-class domestically developed drugs have been approved for market use, and 100-plus have started clinical trials in the US and Europe.