



Chugai In-Licenses Anti-TL1A Antibody RG6631 for the Intractable Diseases Ulcerative Colitis and Crohn's Disease

- Chugai obtained exclusive development and marketing rights in Japan for RG6631, an anti-TL1A antibody under development for ulcerative colitis and Crohn's disease, from Roche.
- With its novel mode of action targeting suppression of inflammation and fibrosis by inhibiting TL1A, RG6631 could offer a promising new therapy for people suffering from ulcerative colitis and Crohn's disease, which are characterized by low rates of remission induction and maintenance, and has the potential to be applied in multiple other diseases.

TOKYO, August 7, 2024 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that it has concluded a license agreement with F. Hoffmann-La Roche Ltd (hereafter "Roche") [Head Office: Basel, Switzerland. Thomas Schinecker] for RG6631, the anti-TL1A antibody, currently in development for ulcerative colitis and Crohn's disease. Under the license agreement between Roche and Chugai, Chugai obtained exclusive rights for the development and marketing of RG6631 in Japan. Roche will receive an upfront fee and milestone payments.

"Ulcerative colitis and Crohn's disease are intractable conditions characterized by cycles of remission and relapse. The recurring symptoms such as diarrhea and abdominal pain often restrict daily life, requiring long-term hospital visits, and the risk of developing colon cancer increases as the disease progresses¹. In addition, treatment methods to maintain remission have not been sufficiently established, and there remains a significant unmet need. Chugai will work closely with Roche to bring RG6631 to patients with Ulcerative colitis and Crohn's disease as soon as possible," said Chugai's President and CEO, Dr. Osamu Okuda.

RG6631 is a potential first-in-class therapy targeting TL1A, is expected to demonstrate high efficacy by simultaneously suppressing inflammation and fibrosis, and has the potential to be applied in multiple other diseases. In the global phase IIb study (TUSCANY-2)² in patients with moderate to severe ulcerative colitis, treatment with RG6631 showed improvement in multiple endpoints including clinical remission in both the induction and maintenance periods. Roche plans to initiate a phase III study by the end of 2024. The phase II study is ongoing for moderate to severe Crohn's disease.

Chugai will continue to effectively utilize the research and development resources of the Roche Group to find innovative new drugs so as to satisfy unmet medical needs.

About Ulcerative Colitis and Crohn's Disease

Ulcerative colitis and Crohn's disease are inflammatory bowel diseases, which refer to chronic or relapsing-remitting inflammatory disorders of the intestinal tract. Symptoms include abdominal pain, frequent bowel movements, diarrhea, weight loss and fatigue^{4,5}. Approximately 80% of patients do not achieve sustained remission⁶, with cycles of relapse and remission being common³. Loss of response to medications can also occur over time, and there remains a need for new therapies, particularly for small bowel and perianal disease⁷.

About Ulcerative Colitis

Ulcerative colitis has a peak onset in the 20s and is a condition in which erosions and ulcers form in the mucosa (innermost layer) of the large intestine. Lesions tend to spread continuously from the rectum and ascend orally, extending to the entire colon at maximum¹. It is one of the designated intractable diseases in Japan (designated intractable disease 97), and the number of medical recipient certificate holders for this disease was 141,387 at the end of year 2022⁸.

About Crohn's Disease

Crohn's disease is mainly seen in younger age groups and is characterized by discontinuous lesions (the presence of normal areas between lesions). Inflammation and ulcers (mucosal defects) primarily affect the small and large intestines, with the terminal ileum being a common site, but can occur in any part of the digestive tract from the mouth to the anus¹. It is one of the designated intractable diseases in Japan (designated intractable disease 96), and the number of medical recipient certificate holders for this disease was 50,184 at the end of year 2022⁸.

Sources

1. Partially modified from Japan Intractable Diseases Information Center. Available from: <https://www.nanbyou.or.jp/>. Accessed June 2024. (Japanese only)
2. Press release by Roivant issued on June 22, 2023
<https://investor.roivant.com/news-releases/news-release-details/roivant-reports-chronic-period-data-rvt-3101-tuscany-2-phase-2b/>
3. The Japanese Gastroenterological Association Guidelines. Available from: <https://www.jsge.or.jp/committees/guideline/guideline/ibd.html>. Accessed June 2024. (Japanese only)
4. Ungaro R, et al. Ulcerative colitis. *Lancet*. 2017; 389(10080):1756-70.
5. Torres J, et al. Crohn's disease. *Lancet*. 2017; 389:1741-55.
6. Sandborn WJ. The Present and Future of inflammatory bowel disease Treatment. *Gastroenterol Hepatol*. 2016; 12:438-41.
7. Renisch W. et. al., *Inflamm Bowel Dis*. 2012 Feb;18(2):201-11., Feagan BG et.al. *N Engl J Med*. 2013 Aug 22;369(8):699-710., Amiot A. et.al. *Therap Adv Gastroenterol*. 2015; 8(2): 66-82.
8. Portal Site of Official Statistics of Japan website (<https://www.e-stat.go.jp/>). Report on Public Health Administration and Services FY2022, Accessed July 2024. (in Japanese only)

###