Nippon Shinyaku Co., Ltd.
Chugai Pharmaceutical Co., Ltd.

Filing of Humanized Anti-CD20 Monoclonal Antibody Gazyva for Additional Indication of Idiopathic Nephrotic Syndrome

- Chugai has filed a regulatory application for approval based on the results of the INShore study, a global Phase III clinical trial conducted in patients with idiopathic nephrotic syndrome.

TOKYO, May 14, 2026 -- Nippon Shinyaku Co., Ltd. (TOKYO: 4516) and Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that Chugai filed a regulatory application with the Ministry of Health, Labour and Welfare (MHLW) for the anti-cancer agent/humanized anti-CD20 monoclonal antibody Gazyva® for Intravenous Infusion 1000 mg [generic name: obinutuzumab (genetical recombination)] for an additional indication of idiopathic nephrotic syndrome (INS).

"We are very pleased to have reached the stage of submitting an application for approval of Gazyva for a new indication, idiopathic nephrotic syndrome." said Nippon Shinyaku's President, Toru Nakai. "We believe that the addition of this indication for Gazyva will help meet unmet needs in clinical practice and further contribute to the treatment of patients."

"Idiopathic nephrotic syndrome often develops during childhood and is characterized by repeated relapses. As a result, adverse effects associated with the long-term use of steroids and immunosuppressants remain a significant challenge, affecting patients' daily lives and future.
In the INShore study, the Gazyva plus oral steroid treatment group demonstrated the potential to reduce patients' treatment burden through sustained remission and steroid reduction compared with conventional therapy. We will continue our efforts toward regulatory approval so that this new treatment option can be delivered to patients as soon as possible," said Dr. Osamu Okuda, Chugai's President and CEO.

The filing is based on results from the INShore study, a global, multicenter, randomized, open-label Phase III clinical trial evaluating the efficacy and safety of Gazyva in patients with idiopathic nephrotic syndrome.

[Reference]
Positive phase III results for Roche's Gazyva/Gazyvaro in children and young adults with idiopathic nephrotic syndrome (Press release from Roche issued on October 30, 2025)
https://www.roche.com/media/releases/med-cor-2025-10-28

About INShore Study[1]
The INShore study is a global, multicenter, randomized, open-label clinical trial conducted in patients aged 2 to 25 years with childhood-onset idiopathic nephrotic syndrome, including frequently relapsing nephrotic syndrome (FRNS) or steroid-dependent nephrotic syndrome (SDNS). The study compared a Gazyva plus oral steroid treatment group with a mycophenolate mofetil (MMF) plus oral steroid treatment group.
The primary endpoint was the proportion of patients who maintained sustained complete remission (SCR) through 52 weeks after treatment initiation.
A statistically significant difference was observed in the primary endpoint. No new safety signals were identified, and the safety profile was consistent with the established safety profile of Gazyva.

About Gazyva (obinutuzumab)
Gazyva is a glycoengineered type II anti-CD20 monoclonal antibody designed to bind to CD20, a protein expressed on certain B cells, but not on stem cells or plasma cells. Gazyva is designed to attack and destroy targeted B cells both directly and together with the body's immune system.
In idiopathic nephrotic syndrome, autoreactive B cells are thought to play a role in disease pathogenesis. Depletion of B cells with Gazyva is expected to suppress autoantibody production, correct abnormal immune responses, reduce glomerular injury, and contribute to sustained remission.
Chugai and Nippon Shinyaku jointly develop and market the product in Japan. The product is currently approved for CD20-positive follicular lymphoma and CD20-positive chronic lymphocytic leukemia (including small lymphocytic lymphoma).

About Idiopathic Nephrotic Syndrome
Idiopathic nephrotic syndrome (INS) is a primary nephrotic syndrome with no identifiable cause and accounts for approximately 60% of all nephrotic syndrome cases.

In pediatric patients, approximately 90% of nephrotic syndrome cases are considered idiopathic[2].
While many childhood-onset cases respond to steroid therapy, some patients experience frequent relapses or steroid dependence, making long-term steroid and immunosuppressant-related adverse events a major clinical unmet need. Depending on disease severity, INS may be designated as an intractable disease (Designated Intractable Disease No.222) in Japan[3].

Sources

1. ClinicalTrials.gov. A Study to Evaluate the Efficacy and Safety of Obinutuzumab Versus MMF in Participants With Childhood Onset Idiopathic Nephrotic Syndrome (INShore) [Internet; cited May 2026]. Available from: https://clinicaltrials.gov/study/NCT05627557
2. The Japanese Society for Pediatric Nephrology. Clinical Practive Guidelines for Pediatric Idiopathic Nephrotic Syndrome 2020. [Internet; cited May 2026]. Available from: https://minds.jcqhc.or.jp/summary/c00605/ (Japanese only)
3. Japan Intractable Diseases Information Center. Primary nephrotic syndrome（Designated intractable disease No.222）[Internet; cited May 2026] https://www.nanbyou.or.jp/entry/4516 (Japanese only)

Contacts	
Chugai Pharmaceutical Co., Ltd. Corporate Communications Dept. Media Relations Group Tel: +81-(0)3-3273-0881 Investor Relations Group Tel: +81-(0)3-3273-0554	Nippon Shinyaku Co., Ltd. Public Relations & Investor Relation Dept. e_mail_kouhou@po.nippon-shinyaku.co.jp

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