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Raludotatug Deruxtecan Demonstrated Clinically Meaningful Response Rates in Patients with Recurrent Platinum-Resistant Ovarian, Primary Peritoneal or Fallopian Tube Cancer in Phase 2 Part of REJOICE-Ovarian01 Phase 2/3 Trial

- An objective response rate of 50.5% was observed with raludotatug deruxtecan across all dose levels in these patients in the phase 2 part of REJOICE-Ovarian01
- Phase 3 part of REJOICE-Ovarian01 to evaluate 5.6 mg/kg dose of raludotatug deruxtecan versus investigator's choice of chemotherapy

Basking Ridge, NJ and Rahway, NJ – (October 19, 2025) – Results from the phase 2 (dose optimization) part of the REJOICE-Ovarian01 phase 2/3 trial showed that raludotatug deruxtecan (R-DXd) demonstrated clinically meaningful response rates in patients with recurrent platinum-resistant ovarian, primary peritoneal or fallopian tube cancer. These data were presented today during a late-breaking proffered paper session (LBA42) at the 2025 European Society for Medical Oncology (#ESMO25) Congress.

Raludotatug deruxtecan is a specifically engineered, potential first-in-class CDH6 directed DXd antibody drug conjugate (ADC) discovered by Daiichi Sankyo (TSE: 4568) and being jointly developed by Daiichi Sankyo and Merck (NYSE: MRK), known as MSD outside of the United States and Canada.

The median overall survival for advanced ovarian cancer following recurrence can be as little as two years, with a five-year survival rate of 31.8% for those with distant stage disease.[1,2] Between 70% and 80% of patients diagnosed with advanced ovarian cancer will experience disease progression following standard treatment with platinum-based chemotherapy regimens, highlighting the need for new treatment options.[3]

A confirmed objective response rate (ORR) of 50.5% (95% confidence interval [CI]: 40.6-60.3) was observed in patients (n=107) with platinum-resistant ovarian cancer receiving raludotatug deruxtecan across three doses (4.8 mg/kg, 5.6 mg/kg and 6.4 mg/kg) as assessed by blinded independent central review (BICR). There were 3 complete responses (CRs) and 51 partial responses (PRs) seen, and a disease control rate (DCR) of 77.6% (95% CI: 68.5–85.1) was observed.

In patients receiving the 5.6 mg/kg dose (n=36), a confirmed ORR of 50.0% (95% CI: 32.9–67.1) was observed as assessed by BICR with two CRs (5.6%), 16 PRs (44.4%) and a DCR of 80.6% (95% CI:

64.0–91.8). Clinically meaningful tumor responses were seen irrespective of dose and across a range of CDH6 expression levels.

The safety profile of raludotatug deruxtecan observed in REJOICE-Ovarian01 is consistent with safety findings from the phase 1 trial with no new safety signals identified. Nausea, anemia, asthenia and neutropenia were the most common treatment-emergent adverse events (TEAEs) across all doses. Treatment discontinuations due to treatment-related TEAEs occurred in 8.3% (n=3), 0.0% (n=0) and 8.6% (n=3) in the 4.8 mg/kg, 5.6mg/kg and 6.4 mg/kg groups, respectively. Grade 3 or higher treatment-related TEAEs occurred in 27.8% (n=10), 30.6% (n=11), and 48.6% (n=17) of patients in the 4.8 mg/kg (n=36), 5.6 mg/kg (n=36), and 6.4 mg/kg (n=35) groups, respectively.

The most common TEAEs (≥10% of total population) in the 5.6 mg/kg cohort included nausea (69.4%), anemia (58.3%), asthenia (50.0%), neutropenia (44.4%), vomiting (33.3%), constipation (27.8%), decreased appetite (25.0%), thrombocytopenia (19.4%), AST increase (16.7%), diarrhea (16.7%) and leukopenia (13.9%). Four (3.7%) interstitial lung disease (ILD)/pneumonitis events were confirmed as treatment-related across all doses as determined by an independent adjudication committee. The majority of ILD events (one with 5.6 mg/kg, two with 6.4 mg/kg) were low grade (grade 1 or 2). One grade ≥3 (4.8 mg/kg) ILD event was reported. Based on these efficacy and safety results, the 5.6 mg/kg dose has been selected for the phase 3 part of the trial.

“When ovarian cancer becomes resistant to platinum-based chemotherapy, treatment options for patients become limited,” said Isabelle Ray-Coquard, MD, PhD, President, ENGOT (European Network of Gynecological Oncology Trial) Group, Trial Leader, National Group of Investigators on the Studies of Ovarian and Breast Cancer (GINECO), and Medical Oncologist, Centre Léon Bérard, Lyon, France. “These promising results from the first part of REJOICE-Ovarian01 suggest that raludotatug deruxtecan may have an important role in treating patients with platinum-resistant ovarian cancer and support further evaluation in the phase 3 portion of this trial.”

“In this dose optimization analysis, rapid responses with impressive disease control have been observed with raludotatug deruxtecan across a range of CDH6 expression levels,” said Ken Takeshita, MD, Global Head, R&D, Daiichi Sankyo. “These results, which contributed to the recent Breakthrough Therapy Designation in the U.S., reinforce the potential for raludotatug deruxtecan to become a new treatment option for certain types of patients with platinum-resistant ovarian cancer.”

“While we have seen targeted treatment advancements and improved outcomes in ovarian cancer in recent years, there is still a high unmet need for additional options for patients,” said Eliav Barr, MD, Senior Vice President, Head of Global Clinical Development and Chief Medical Officer, Merck

Research Laboratories. “CDH6 is highly expressed in ovarian cancer, which underscores the potential of raludotatug deruxtecan to make an impact.”

In September 2025, raludotatug deruxtecan was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration for the treatment of adult patients with platinum-resistant epithelial ovarian, primary peritoneal or fallopian tube cancers expressing CDH6 who have received prior treatment with bevacizumab.

Median follow-up for the 4.8-mg/kg, 5.6-mg/kg and 6.4-mg/kg cohorts was 5.6 months (95% CI: 4.7–6.3), 5.6 months (95% CI: 4.6–5.8), and 5.2 months (95% CI: 4.9–5.8), respectively. A majority of patients (51.4%) in REJOICE-Ovarian01 received three prior lines of treatment, including bevacizumab (n=89; 83.2%), PARP inhibitor (n=75; 70.1%) and mirvetuximab soravtansine (n=3; 2.8%). As of the data cut-off of February 26, 2025, 66 patients (61.7%) remain on treatment with raludotatug deruxtecan.

Summary of REJOICE-Ovarian01 Results

Efficacy Measure	Raludotatug Deruxtecan Across 4.8, 5.6 and 6.4 mg/kg (n=107)	Raludotatug Deruxtecan 6.4 mg/kg (n=35)	Raludotatug Deruxtecan 5.6 mg/kg (n=36)	Raludotatug Deruxtecan 4.8 mg/kg (n=36)
Confirmed ORR, % (95% CI) [1]	50.5% (40.6–60.3)	57.1% (39.4–73.7)	50.0% (32.9–67.1)	44.4% (27.9–61.9)
CR, n (%)	3 (2.8%)	0	2 (5.6%)	1 (2.8%)
PR, n (%)	51 (47.7%)	20 (57.1%)	16 (44.4%)	15 (41.7%)
SD, n (%)	42 (39.3%)	10 (28.6%)	15 (41.7%)	17 (47.2%)
PD, n (%)	8 (7.5%)	4 (11.4%)	2 (5.6%)	2 (5.6%)
NE, n (%)	3 (2.8%)	1 (2.9%)[2]	1 (2.8%)[3]	1 (2.8%)[2]
DCR, % (95% CI)	77.6% (68.5–85.1)	77.1% (59.9–89.6)	80.6% (64.0–91.8)	75.0% (57.8–87.9)
TTR, weeks, median (range)	7.1 weeks (5.1–19.1)	7.2 weeks (5.3–19.1)	6.6 weeks (5.1–18.3)	7.1 weeks (5.4–18.7)

Data cutoff: February 26, 2025.
[1]As accessed by BICR per RECIST 1.1 [2]Patient had no baseline tumor assessment by BICR. [3]Patient had no adequate post-baseline tumor assessment by BICR.
BICR, blinded independent central review; CR, complete response; DCR, disease control rate; ORR, objective response rate; PD, progressive disease; PR, partial response; RECIST 1.1, Response Evaluation Criteria in Solid Tumors version 1.1; SD, stable disease; TTR, time to response.

About REJOICE-Ovarian01

REJOICE-Ovarian01 is a global, multicenter, randomized, open-label phase 2/3 trial evaluating the efficacy and safety of investigational raludotatug deruxtecan in patients with platinum-resistant, high-grade ovarian, primary peritoneal or fallopian tube cancer, with disease progression following at least one but no more than three prior lines of systemic therapy, including prior treatment with

mirvetuximab soravtansine for those with documented high-folate receptor alpha expression. Maintenance therapy (e.g., bevacizumab, poly ADP-ribose polymerase [PARP] inhibitors) is considered part of the preceding line of therapy.

The phase 2 part of REJOICE-Ovarian01 is assessing the safety and tolerability of three doses of raludotatug deruxtecan (4.8 mg/kg, 5.6 mg/kg, or 6.4 mg/kg) to identify the recommended dose for the phase 3 part of the trial. The primary endpoint of the phase 2 part of the trial is ORR as assessed by BICR. Key secondary endpoints include ORR as assessed by investigator, DoR, PFS and DCR – all assessed by both BICR and investigator.

The phase 3 part of REJOICE-Ovarian01 is assessing the efficacy and safety of raludotatug deruxtecan at the selected dose (5.6 mg/kg) compared to investigator's choice of chemotherapy (paclitaxel, pegylated liposomal doxorubicin, gemcitabine or topotecan). The dual primary endpoints of the phase 3 part of the trial are ORR and PFS as assessed by BICR. Secondary endpoints include PFS and ORR as assessed by investigator, DoR and DCR as assessed by both BICR and investigator, and OS. Pharmacokinetic and biomarker endpoints also will be assessed in both parts of the trial.

REJOICE-Ovarian01 is expected to enroll approximately 710 patients across Asia, Europe, North America, and Oceania. For more information, please visit ClinicalTrials.gov.

About Ovarian Cancer

More than 324,000 women were diagnosed with ovarian cancer worldwide in 2022.[4] The median overall survival for advanced ovarian cancer following recurrence can be as little as two years, with a five-year survival rate of 31.8% for those with distant stage disease.[1,2]

The introduction of targeted therapies has expanded treatment options and improved survival outcomes for some patients with ovarian cancer, but additional options are needed for patients with tumors that progress on available medicines.[5] Between 70% and 80% of patients diagnosed with advanced ovarian cancer will experience disease progression following standard treatment with platinum-based chemotherapy regimens.[3] For patients who develop platinum-resistant ovarian cancer, defined as disease progression less than six months after completion of last platinum-based chemotherapy, prognosis is particularly poor and treatment options are limited.[6,7]

About CDH6

CDH6 (human cadherin-6) is a cadherin family protein overexpressed in several cancers, including ovarian tumors.[8] An estimated 65% to 94% of patients with ovarian cancer have tumors that express

CDH6.[9,10,11] In addition, CDH6 expression is observed more frequently in high-grade serous carcinomas.[9, 10,11] There is currently no CDH6 directed medicine approved for treatment of any cancer.

About Raludotatug Deruxtecan

Raludotatug deruxtecan is an investigational, potential first-in-class CDH6 directed ADC. Designed using Daiichi Sankyo's proprietary DXd ADC Technology, raludotatug deruxtecan is comprised of a humanized anti-CDH6 IgG1 monoclonal antibody attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers.

About the Daiichi Sankyo and Merck Collaboration

Daiichi Sankyo and Merck (known as MSD outside of the United States and Canada) entered into a global collaboration in October 2023 to jointly develop and commercialize patritumab deruxtecan (HER3-DXd), ifinatamab deruxtecan (I-DXd) and raludotatug deruxtecan (R-DXd), except in Japan where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo will be solely responsible for manufacturing and supply. In August 2024, the global co-development and co-commercialization agreement was expanded to include gocatamig (MK-6070/DS3280), which the companies will jointly develop and commercialize worldwide, except in Japan where Merck & Co., Inc., Rahway, N.J., USA will maintain exclusive rights. Merck & Co., Inc., Rahway, N.J., USA will be solely responsible for manufacturing and supply for gocatamig.

About the ADC Portfolio of Daiichi Sankyo

The Daiichi Sankyo ADC portfolio consists of seven ADCs in clinical development crafted from two distinct ADC technology platforms discovered in-house by Daiichi Sankyo.

The ADC platform furthest in clinical development is Daiichi Sankyo's DXd ADC Technology where each ADC consists of a monoclonal antibody attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers. The DXd ADC portfolio currently consists of ENHERTU®, a HER2 directed ADC, and DATROWAY®, a TROP2 directed ADC, which are being jointly developed and commercialized globally with AstraZeneca. Patritumab deruxtecan (HER3-DXd), a HER3 directed ADC, ifinatamab deruxtecan (I-DXd), a B7-H3 directed ADC, and raludotatug deruxtecan (R-DXd), a CDH6 directed ADC, are being jointly developed and commercialized globally with Merck & Co., Inc., Rahway, N.J., USA. DS-3939, a TA-MUC1 directed ADC, is being developed by Daiichi Sankyo.

The second Daiichi Sankyo ADC platform consists of a monoclonal antibody attached to a modified pyrrolobenzodiazepine (PBD) payload. DS-9606, a CLDN6 directed PBD ADC, is the first of several planned ADCs in clinical development utilizing this platform.

Ifinatamab deruxtecan, patritumab deruxtecan, raludotatug deruxtecan, DS-3939 and DS-9606 are investigational medicines that have not been approved for any indication in any country. Safety and efficacy have not been established.

About Daiichi Sankyo

Daiichi Sankyo is an innovative global healthcare company contributing to the sustainable development of society that discovers, develops and delivers new standards of care to enrich the quality of life around the world. With more than 120 years of experience, Daiichi Sankyo leverages its world-class science and technology to create new modalities and innovative medicines for people with cancer, cardiovascular and other diseases with high unmet medical needs. For more information, please visit www.daiichisankyo.com.

Merck's Focus on Cancer

Every day, we follow the science as we work to discover innovations that can help patients, no matter what stage of cancer they have. As a leading oncology company, we are pursuing research where scientific opportunity and medical need converge, underpinned by our diverse pipeline of more than 25 novel mechanisms. With one of the largest clinical development programs across more than 30 tumor types, we strive to advance breakthrough science that will shape the future of oncology. By addressing barriers to clinical trial participation, screening and treatment, we work with urgency to reduce disparities and help ensure patients have access to high-quality cancer care. Our unwavering commitment is what will bring us closer to our goal of bringing life to more patients with cancer. For more information, visit www.merck.com/research/oncology/.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.merck.com and connect with us on X (formerly Twitter), Facebook, Instagram, YouTube and LinkedIn.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2024, and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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