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Daiichi-Sankyo

Press Release

Daiichi Sankyo to Present New Breast Cancer Data Across DXd ADC Portfolio at 2021 SABCS

- Additional analyses of DESTINY-Breast03 trial of ENHERTU and updated results from triple negative breast cancer cohort of TROPION-PanTumor01 trial of datopotamab deruxtecan to be highlighted
- Daiichi Sankyo to hold annual R&D Day following SABCS to provide updates across entire R&D portfolio

Munich and Basking Ridge, NJ – (December 1, 2021) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) will present new breast cancer research data across its DXd ADC portfolio at the 2021 San Antonio Breast Cancer Symposium (#SABCS21) to be held December 7 to 10, 2021.

Additional analyses from the head-to-head DESTINY-Breast03 phase 3 trial of ENHERTU® (trastuzumab deruxtecan) versus trastuzumab emtansine (T-DM1) in patients with previously treated HER2 positive metastatic breast cancer along with updated results from the triple negative breast cancer (TNBC) cohort of the TROPION-PanTumor01 phase 1 trial of datopotamab deruxtecan (Dato-DXd) will be highlighted in oral presentations. Trials-in-progress from other ongoing breast cancer trials in the DESTINY clinical development program of ENHERTU as well as a collaborative window of opportunity study conducted by SOLTI Breast Cancer Research Group with patritumab deruxtecan (HER3-DXd) in patients with previously untreated early stage breast cancer also will be featured.

"Our goal is to continuously improve the standard of care in patients with breast cancer across different subtypes and treatment settings including neoadjuvant, adjuvant and metastatic disease with our innovative ADC portfolio," said Ken Takeshita, MD, Global Head, R&D, Daiichi Sankyo. "We look forward to presenting updates from the DESTINY-Breast03 trial and TROPION-PanTumor01 trial, two important trials that demonstrate the strength and potential of our DXd ADC technology in creating transformative medicines for patients with cancer."

Following SABCS, Daiichi Sankyo will hold its annual R&D Day for investors and analysts on Tuesday, December 14, 2021 at 5:30 pm EST/Wednesday, December 15, 2021 at 7:30 am JST. Company executives will provide an overview of Daiichi Sankyo's research data presented at SABCS and the American Society of Hematology (ASH) annual meetings, provide updates on the company's R&D strategy and address questions from investors and analysts.

Following is an overview of breast cancer research data from the DXd ADC portfolio of Daiichi Sankyo to be presented at SABCS 2021:

Presentation Title	Author	Abstract #	Presentation Details
ENHERTU (T-DXd)			
Clinical Data			
Trastuzumab deruxtecan (T-DXd) vs. trastuzumab emtansine (T-DM1) in patients with HER2 positive metastatic breast cancer: results of the randomized phase 3 study: DESTINY-Breast03	S. Hurvitz	GS3-01	Oral Presentation; General Session: 3 Thursday, December 9 8:45 AM – 11:30 AM CST
Trastuzumab deruxtecan (T-DXd) in previously treated HER2 positive metastatic or unresectable breast cancer: first real-life data from the cohort temporary authorization for use program in France	T. Petit	P2-13-26	Poster Poster Session 2: Treatment - Therapeutic Strategies: HER2 Targeted Therapy Wednesday, December 8 5:00 PM – 6:30 PM CST
Trials-In-Progress			
Trastuzumab deruxtecan (T-DXd) vs. trastuzumab emtansine (T-DM1) in high-risk patients with HER2 positive, residual invasive early breast cancer after neoadjuvant therapy: a randomized, phase 3 trial: DESTINY-Breast05	C.E. Geyer, Jr.	OT1-02-03	Poster Ongoing Trials Poster Session 1: Antibody-Drug Conjugates Wednesday, December 8 5:00 PM – 6:30 PM CST
Phase 3 study of trastuzumab deruxtecan (T-DXd) with or without pertuzumab vs. a taxane, trastuzumab and pertuzumab in first-line, human epidermal growth factor receptor 2 positive metastatic breast cancer: DESTINY-Breast09	S.M. Tolaney	OT1-14-02	Poster Ongoing Trials Poster Session 1: HER2 Mab Wednesday, December 8 5:00 PM – 6:30 PM CST
A phase 3, open-label trial of neoadjuvant trastuzumab deruxtecan (T-DXd) monotherapy or T-DXd followed by THP compared with ddAC-THP in patients with high-risk HER2 positive early-stage breast cancer: DESTINY-Breast11	N. Harbeck	OT1-12-04	Poster Ongoing Trials Poster Session 1: HER2 Wednesday, December 8 5:00 PM – 6:30 PM CST
Open-label, multinational, multicenter, phase 3b/4 study of trastuzumab deruxtecan (T-DXd) in patients with or without baseline brain metastasis with previously treated advanced/metastatic human epidermal growth factor receptor 2 positive breast cancer: DESTINY-Breast12	N.U. Lin	OT2-26-01	Poster Ongoing Trials Poster Session 2: Targeted Therapy - T-DXd, Brain Mets Thursday, December 9 5:00 PM – 6:30 PM CST
Randomized study comparing electronic patient reported outcomes monitoring with routine follow-up during trastuzumab deruxtecan (T-DXd) treatment in patients with inoperable or metastatic breast cancer (PRO-DUCE study)	T. Sangai	OT1-12-08	Poster Ongoing Trials Poster Session 1: HER2 Wednesday, December 8 5:00 PM – 6:30 PM CST
Pre-Clinical Data			
Activity and tolerability of combination of trastuzumab deruxtecan (T-DXd) with the pan-AKT inhibitor capivasertib in preclinical HER2 positive and HER2 low breast cancer models	A. Bashi Cheraghchi	P2-13-23	Poster Poster Session 2: Treatment - Therapeutic Strategies: HER2 Targeted Therapy Wednesday, December 8 5:00 PM – 6:30 PM CST

Presentation Title	Author	Abstract #	Presentation Details
Activity and tolerability of combination of trastuzumab deruxtecan (T-DXd) with olaparib in preclinical HER2 positive and HER2 low breast cancer models	T. Proia	P2-13-18	Poster Poster Session 2: Treatment - Therapeutic Strategies: HER2 Targeted Therapy Wednesday, December 8 5:00 PM – 6:30 PM CST
Datopotamab Deruxtecan (Dato-DXd)			
Datopotamab deruxtecan (Dato-DXd) in advanced/metastatic HER2 negative breast cancer: Results from the phase 1 TROPION-PanTumor01 study	I. Krop	GS1-05	Oral Presentation; General Session 1 Tuesday, December 7 8:15 AM – 10:45 AM CST
Patritumab Deruxtecan (HER3-DXd) – Collaborative Studies			
Activity of patritumab deruxtecan (HER3-DXd), a HER3 directed antibody drug conjugate, in early breast cancer according to ERBB3 expression: Interim analysis results of a window of opportunity study (SOLTI-1805 TOT-HER3)	A. Prat	PD13-04	Spotlight Poster Discussion Spotlight Poster Discussion 13: Novel Therapeutics Friday, December 10 7:00 AM – 8:30 AM CST
Antitumor activity of patritumab deruxtecan (HER3-DXd), a HER3 directed antibody drug conjugate across a diverse panel of breast cancer patient-derived xenografts	A. Òdena	P5-13-14	Poster Poster Session 5: Prognostic and Predictive Factors: Predictive Biomarkers for Targeted Therapies Friday, December 10 7:00 AM – 8:30 AM CST

About the DXd ADC Portfolio of Daiichi Sankyo

The DXd ADC portfolio of Daiichi Sankyo consists of six ADCs with five in clinical development across multiple types of cancer. The company's three lead ADCs include ENHERTU, a HER2 directed ADC, datopotamab deruxtecan (Dato-DXd), a TROP2 directed ADC, which are being jointly developed and commercialized globally with AstraZeneca; and patritumab deruxtecan (HER3-DXd), a HER3 directed ADC. Two additional ADCs, DS-7300 (B7-H3) and DS-6000 (CDH6), are being developed through a strategic collaboration with Sarah Cannon Research Institute.

Each ADC is designed using Daiichi Sankyo's proprietary DXd ADC technology to target and deliver chemotherapy inside cancer cells that express a specific cell surface antigen. Each ADC is composed of a monoclonal antibody attached to a topoisomerase I inhibitor payload (an exatecan derivative, DXd) via a tetrapeptide-based cleavable linker.

ENHERTU (5.4 mg/kg) (trastuzumab deruxtecan; fam-trastuzumab deruxtecan-nxki in U.S. only) is approved in more than 30 countries for the treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti-HER2 based regimens based on the results from the DESTINY-Breast01 trial.

ENHERTU (6.4 mg/kg) is approved in Israel, Japan, Singapore and U.S. for the treatment of adult patients with locally advanced or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen based on the results from the DESTINY-Gastric01 trial. A

Type II Variation is currently under review by the European Medicines Agency (EMA) for the treatment of adult patients with locally advanced or metastatic HER2 positive gastric or GEJ adenocarcinoma who have received a prior anti-HER2-based regimen.

ENHERTU is approved in the U.S. with Boxed WARNINGS for Interstitial Lung Disease and Embryo-Fetal Toxicity. For more information, please see the accompanying full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

Datopotamab deruxtecan, patritumab deruxtecan, DS-7300 and DS-6000 are investigational medicines that have not been approved for any indication in any country. Safety and efficacy have not been established.

U.S. Important Safety Information for ENHERTU

Indications
ENHERTU is a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with:

- Unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

  This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

- Locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen.

WARNING: INTERSTITIAL LUNG DISEASE and EMBRYO-FETAL TOXICITY

- **Interstitial lung disease (ILD) and pneumonitis, including fatal cases, have been reported with ENHERTU. Monitor for and promptly investigate signs and symptoms including cough, dyspnea, fever, and other new or worsening respiratory symptoms. Permanently discontinue ENHERTU in all patients with Grade 2 or higher ILD/pneumonitis. Advise patients of the risk and to immediately report symptoms.**
- **Exposure to ENHERTU during pregnancy can cause embryo-fetal harm. Advise patients of these risks and the need for effective contraception.**

Contraindications
None.

Warnings and Precautions
Interstitial Lung Disease / Pneumonitis
Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ENHERTU. Advise patients to immediately report cough, dyspnea, fever, and/or any new or worsening respiratory symptoms. Monitor patients for signs and symptoms of ILD. Promptly investigate evidence of ILD. Evaluate patients with suspected ILD by radiographic imaging. Consider consultation with a pulmonologist. For asymptomatic ILD/pneumonitis (Grade 1), interrupt ENHERTU until resolved to Grade 0,

then if resolved in ≤28 days from date of onset, maintain dose. If resolved in >28 days from date of onset, reduce dose one level. Consider corticosteroid treatment as soon as ILD/pneumonitis is suspected (e.g., ≥0.5 mg/kg/day prednisolone or equivalent). For symptomatic ILD/pneumonitis (Grade 2 or greater), permanently discontinue ENHERTU. Promptly initiate systemic corticosteroid treatment as soon as ILD/pneumonitis is suspected (e.g., ≥1 mg/kg/day prednisolone or equivalent) and continue for at least 14 days followed by gradual taper for at least 4 weeks.

Metastatic Breast Cancer
In clinical studies, of the 234 patients with unresectable or metastatic HER2-positive breast cancer treated with ENHERTU 5.4 mg/kg, ILD occurred in 9% of patients. Fatal outcomes due to ILD and/or pneumonitis occurred in 2.6% of patients treated with ENHERTU. Median time to first onset was 4.1 months (range: 1.2 to 8.3).

Locally Advanced or Metastatic Gastric Cancer
In DESTINY-Gastric01, of the 125 patients with locally advanced or metastatic HER2-positive gastric or GEJ adenocarcinoma treated with ENHERTU 6.4 mg/kg, ILD occurred in 10% of patients. Median time to first onset was 2.8 months (range: 1.2 to 21.0).

Neutropenia
Severe neutropenia, including febrile neutropenia, can occur in patients treated with ENHERTU. Monitor complete blood counts prior to initiation of ENHERTU and prior to each dose, and as clinically indicated. For Grade 3 neutropenia (Absolute Neutrophil Count [ANC] <1.0 to 0.5 x 10^9/L) interrupt ENHERTU until resolved to Grade 2 or less, then maintain dose. For Grade 4 neutropenia (ANC <0.5 x 10^9/L) interrupt ENHERTU until resolved to Grade 2 or less. Reduce dose by one level. For febrile neutropenia (ANC <1.0 x 10^9/L and temperature >38.3ºC or a sustained temperature of ≥38ºC for more than 1 hour), interrupt ENHERTU until resolved. Reduce dose by one level.

Metastatic Breast Cancer
In clinical studies, of the 234 patients with unresectable or metastatic HER2-positive breast cancer who received ENHERTU 5.4mg/kg, a decrease in neutrophil count was reported in 62% of patients. Sixteen percent had Grade 3 or 4 decrease in neutrophil count. Median time to first onset of decreased neutrophil count was 23 days (range: 6 to 547). Febrile neutropenia was reported in 1.7% of patients.

Locally Advanced or Metastatic Gastric Cancer
In DESTINY-Gastric01, of the 125 patients with locally advanced or metastatic HER2-positive gastric or GEJ adenocarcinoma treated with ENHERTU 6.4 mg/kg, a decrease in neutrophil count was reported in 72% of patients. Fifty-one percent had Grade 3 or 4 decreased neutrophil count. Median time to first onset of decreased neutrophil count was 16 days (range: 4 to 187). Febrile neutropenia was reported in 4.8% of patients.

Left Ventricular Dysfunction
Patients treated with ENHERTU may be at increased risk of developing left ventricular dysfunction. Left ventricular ejection fraction (LVEF) decrease has been observed with anti-HER2 therapies, including ENHERTU. In the 234 patients with unresectable or metastatic HER2-positive breast cancer who received ENHERTU, two cases (0.9%) of asymptomatic LVEF decrease were reported. In DESTINY-Gastric01, of the 125 patients with locally advanced or metastatic HER2-positive gastric or GEJ adenocarcinoma treated with ENHERTU 6.4 mg/kg, no clinical adverse events of heart failure were reported; however, on echocardiography, 8% were found to have asymptomatic Grade 2 decrease in LVEF. Treatment with ENHERTU has not been studied in patients with a history of clinically significant cardiac disease or LVEF <50% prior to initiation of treatment.

Assess LVEF prior to initiation of ENHERTU and at regular intervals during treatment as clinically indicated. When LVEF is >45% and absolute decrease from baseline is 10-20%, continue treatment with ENHERTU. When LVEF is 40-45% and absolute decrease from baseline is <10%, continue treatment with ENHERTU and repeat LVEF assessment within 3 weeks. When LVEF is 40-45% and absolute decrease from baseline is 10-20%, interrupt ENHERTU and repeat LVEF assessment within 3 weeks. If LVEF has not recovered to within 10% from baseline, permanently discontinue ENHERTU. If LVEF recovers to within 10% from baseline,

resume treatment with ENHERTU at the same dose. When LVEF is <40% or absolute decrease from baseline is >20%, interrupt ENHERTU and repeat LVEF assessment within 3 weeks. If LVEF of <40% or absolute decrease from baseline of >20% is confirmed, permanently discontinue ENHERTU. Permanently discontinue ENHERTU in patients with symptomatic congestive heart failure.

Embryo-Fetal Toxicity

ENHERTU can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risks to a fetus. Verify the pregnancy status of females of reproductive potential prior to the initiation of ENHERTU. Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of ENHERTU. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months after the last dose of ENHERTU.

Additional Dose Modifications

Thrombocytopenia

For Grade 3 thrombocytopenia (platelets <50 to 25 x 10^9/L) interrupt ENHERTU until resolved to Grade 1 or less, then maintain dose. For Grade 4 thrombocytopenia (platelets <25 x 10^9/L) interrupt ENHERTU until resolved to Grade 1 or less. Reduce dose by one level.

Adverse Reactions

Metastatic Breast Cancer

The safety of ENHERTU was evaluated in a pooled analysis of 234 patients with unresectable or metastatic HER2-positive breast cancer who received at least one dose of ENHERTU 5.4 mg/kg in DESTINY-Breast01 and Study DS8201-A-J101. ENHERTU was administered by intravenous infusion once every three weeks. The median duration of treatment was 7 months (range: 0.7 to 31).

Serious adverse reactions occurred in 20% of patients receiving ENHERTU. Serious adverse reactions in >1% of patients who received ENHERTU were interstitial lung disease, pneumonia, vomiting, nausea, cellulitis, hypokalemia, and intestinal obstruction. Fatalities due to adverse reactions occurred in 4.3% of patients including interstitial lung disease (2.6%), and the following events occurred in one patient each (0.4%): acute hepatic failure/acute kidney injury, general physical health deterioration, pneumonia, and hemorrhagic shock.

ENHERTU was permanently discontinued in 9% of patients, of which ILD accounted for 6%. Dose interruptions due to adverse reactions occurred in 33% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose interruption were neutropenia, anemia, thrombocytopenia, leukopenia, upper respiratory tract infection, fatigue, nausea, and ILD. Dose reductions occurred in 18% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose reduction were fatigue, nausea, and neutropenia.

The most common (≥20%) adverse reactions, including laboratory abnormalities, were nausea (79%), white blood cell count decreased (70%), hemoglobin decreased (70%), neutrophil count decreased (62%), fatigue (59%), vomiting (47%), alopecia (46%), aspartate aminotransferase increased (41%), alanine aminotransferase increased (38%), platelet count decreased (37%), constipation (35%), decreased appetite (32%), anemia (31%), diarrhea (29%), hypokalemia (26%), and cough (20%).

Locally Advanced or Metastatic Gastric Cancer

The safety of ENHERTU was evaluated in 187 patients with locally advanced or metastatic HER2-positive gastric or GEJ adenocarcinoma in DESTINY-Gastric01. Patients intravenously received at least one dose of either ENHERTU (N=125) 6.4 mg/kg once every three weeks or either irinotecan (N=55) 150 mg/m^2 biweekly or paclitaxel (N=7) 80 mg/m^2 weekly for 3 weeks. The median duration of treatment was 4.6 months (range: 0.7 to 22.3) in the ENHERTU group and 2.8 months (range: 0.5 to 13.1) in the irinotecan/paclitaxel group.

Serious adverse reactions occurred in 44% of patients receiving ENHERTU 6.4 mg/kg. Serious adverse reactions in >2% of patients who received ENHERTU were decreased appetite, ILD, anemia, dehydration, pneumonia, cholestatic jaundice, pyrexia, and tumor hemorrhage. Fatalities due to adverse reactions occurred in 2.4% of

patients: disseminated intravascular coagulation, large intestine perforation, and pneumonia occurred in one patient each (0.8%).

ENHERTU was permanently discontinued in 15% of patients, of which ILD accounted for 6%. Dose interruptions due to adverse reactions occurred in 62% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose interruption were neutropenia, anemia, decreased appetite, leukopenia, fatigue, thrombocytopenia, ILD, pneumonia, lymphopenia, upper respiratory tract infection, diarrhea, and hypokalemia. Dose reductions occurred in 32% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose reduction were neutropenia, decreased appetite, fatigue, nausea, and febrile neutropenia.

The most common (≥20%) adverse reactions, including laboratory abnormalities, were hemoglobin decreased (75%), white blood cell count decreased (74%), neutrophil count decreased (72%), lymphocyte count decreased (70%), platelet count decreased (68%), nausea (63%), decreased appetite (60%), anemia (58%), aspartate aminotransferase increased (58%), fatigue (55%), blood alkaline phosphatase increased (54%), alanine aminotransferase increased (47%), diarrhea (32%), hypokalemia (30%), vomiting (26%), constipation (24%), blood bilirubin increased (24%), pyrexia (24%), and alopecia (22%).

Use in Specific Populations

- **Pregnancy:** ENHERTU can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risks to a fetus. There are clinical considerations if ENHERTU is used in pregnant women, or if a patient becomes pregnant within 7 months following the last dose of ENHERTU.
- **Lactation:** There are no data regarding the presence of ENHERTU in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with ENHERTU and for 7 months after the last dose.
- **Females and Males of Reproductive Potential:** Pregnancy testing: Verify pregnancy status of females of reproductive potential prior to initiation of ENHERTU. Contraception: *Females*: ENHERTU can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 7 months following the last dose. *Males*: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months following the last dose. Infertility: ENHERTU may impair male reproductive function and fertility.
- **Pediatric Use:** Safety and effectiveness of ENHERTU have not been established in pediatric patients.
- **Geriatric Use:** Of the 234 patients with HER2-positive breast cancer treated with ENHERTU 5.4 mg/kg, 26% were ≥65 years and 5% were ≥75 years. No overall differences in efficacy were observed between patients ≥65 years of age compared to younger patients. There was a higher incidence of Grade 3-4 adverse reactions observed in patients aged ≥65 years (53%) as compared to younger patients (42%). Of the 125 patients with locally advanced or metastatic HER2-positive gastric or GEJ adenocarcinoma treated with ENHERTU 6.4 mg/kg in DESTINY-Gastric01, 56% were ≥65 years and 14% were ≥75 years. No overall differences in efficacy or safety were observed between patients ≥65 years of age compared to younger patients.
- **Hepatic Impairment:** In patients with moderate hepatic impairment, due to potentially increased exposure, closely monitor for increased toxicities related to the topoisomerase inhibitor.

To report SUSPECTED ADVERSE REACTIONS, contact Daiichi Sankyo, Inc. at 1-877-437-7763 or FDA at 1-800-FDA-1088 or fda.gov/medwatch.

Please see accompanying full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

About Daiichi Sankyo in Oncology

The oncology portfolio of Daiichi Sankyo is powered by our team of world-class scientists that push beyond traditional thinking to create transformative medicines for people with cancer. Anchored by our DXd antibody drug conjugate (ADC) technology, our research engines include biologics, medicinal chemistry, modality and

other research laboratories in Japan, and Plexxikon, our small molecule structure-guided R&D center in the U.S. We also work alongside leading academic and business collaborators to further advance the understanding of cancer as Daiichi Sankyo builds towards our ambitious goal of becoming a global leader in oncology by 2025.

About Daiichi Sankyo

Daiichi Sankyo is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose "to contribute to the enrichment of quality of life around the world." In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical needs. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation to realize our 2030 Vision to become an "Innovative Global Healthcare Company Contributing to the Sustainable Development of Society." For more information, please visit www.daiichisankyo.com.

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