Now FDA approved: **RITUXAN HYCELA**™ (rituximab/hyaluronidase human) for Subcutaneous Injection

Same antibody as RITUXAN® (rituximab), delivered subcutaneously with hyaluronidase human

PLEASE JOIN US FOR A CLINICAL OVERVIEW OF RITUXAN HYCELA

Date: December 5, 2017 | **Time:** 6:30 - 7:30 PM

PRESENTED BY:

Karolina Faysman, RN, MSN, ANP

UCLA Medical Center

Los Angeles, CA

DATE AND SCHEDULE:

Tuesday, December 5, 2017

6:00 pm Registration

6:30 pm Program and meal

HOSTED BY:

Kimberly Arino-Lacock

Genentech

LOCATION:

Le Papillon Restaurant

410 Saratoga Avenue

San Jose, CA 05129

REGISTRATION:

Please register for this event by **12/1/2017.**
Register online at www.genersvp.com with event code **PRF81118** or RSVP to
Kimberly Arino-Lacock **707-290-5766**
arinolacock.kimberly@gene.com

Learn about RITUXAN HYCELA

A subcutaneously administered combination of rituximab and hyaluronidase human

- Indications and important safety information
- Proposed mechanism of action
- Dosing and administration
- Results from 4 clinical studies

INDICATIONS

RITUXAN HYCELA™ (rituximab/hyaluronidase human) is indicated for the treatment of adult patients with:

- Relapsed or refractory, follicular lymphoma (FL) as a single agent
- Previously untreated follicular lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy
- Non-progressing (including stable disease) follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy
- Previously untreated diffuse large B-cell lymphoma (DLBCL) in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens
- Previously untreated and previously treated chronic lymphocytic leukemia (CLL) in combination with fludarabine and cyclophosphamide (FC)

Initiate treatment with RITUXAN HYCELA only after patients have received at least one full dose of RITUXAN®

RITUXAN HYCELA is not indicated for the treatment of non-malignant conditions

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS: SEVERE MUCOCUTANEOUS REACTIONS, HEPATITIS B VIRUS REACTIVATION and PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

- **Severe Mucocutaneous Reactions: Severe, including fatal, mucocutaneous reactions can occur in patients receiving rituximab-containing products, including RITUXAN HYCELA**
- **Hepatitis B Virus (HBV) Reactivation: HBV reactivation can occur in patients treated with rituximab-containing products, including RITUXAN HYCELA, in some cases resulting in fulminant hepatitis, hepatic failure, and death. Screen all patients for HBV infection before treatment initiation, and monitor patients during and after treatment with RITUXAN HYCELA. Discontinue RITUXAN HYCELA and concomitant medications in the event of HBV reactivation**
- **Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving rituximab-containing products, including RITUXAN HYCELA**

Please see the following page and accompanying full Prescribing Information, including **BOXED WARNINGS** and Medication Guide, for additional Important Safety Information.

RituxanHYCELA™
rituximab/hyaluronidase human
subcutaneous injection
1,400 mg/23,400 Units
1,600 mg/26,800 Units

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IMPORTANT SAFETY INFORMATION (CONT'D)

ADDITIONAL WARNINGS AND PRECAUTIONS

Hypersensitivity and Other Administration Reactions

Systemic Reactions

- Patients must receive at least one full dose of RITUXAN before receiving RITUXAN HYCELA due to the higher risk of hypersensitivity and other acute reactions during the first infusion. Beginning therapy with RITUXAN allows management of hypersensitivity and other administration reactions by slowing or stopping the intravenous infusion
- Rituximab-containing products, including RITUXAN HYCELA, are associated with hypersensitivity and other administration reactions. This set of reactions includes syndrome of cytokine release, tumor lysis syndrome, and anaphylactic and hypersensitivity reactions. They are not specifically related to the route of administration of a rituximab-containing product
- Severe infusion-related reactions with fatal outcome have been reported with the use of RITUXAN, with an onset of 30 minutes to 2 hours after starting the first infusion. Anaphylactic and other hypersensitivity reactions can also occur. In contrast to cytokine release syndrome, true hypersensitivity reactions typically occur within minutes after starting infusion
- Cytokine release syndrome may occur within 1-2 hours of initiating the infusion. Patients with a history of pulmonary insufficiency or those with pulmonary tumor infiltration may be at a greater risk of poor outcome. Rituximab product administration should be interrupted immediately and aggressive symptomatic treatment initiated
- Interrupt RITUXAN HYCELA administration immediately when observing signs of a severe reaction and initiate aggressive symptomatic treatment. Closely monitor: those with pre-existing cardiac or pulmonary conditions, those who experienced prior cardiopulmonary adverse reactions, and those with high numbers of circulating malignant cells (≥25,000/mm^3)
- Premedicate patients with an antihistamine and acetaminophen and consider glucocorticoids prior to each administration of RITUXAN HYCELA. Observe patients for at least 15 minutes following RITUXAN HYCELA. A longer period may be appropriate in patients with an increased risk of hypersensitivity reactions

Local Cutaneous Reactions

- Local cutaneous reactions, including injection site reactions, have been reported in patients receiving RITUXAN HYCELA

Tumor Lysis Syndrome (TLS)

- TLS can occur within 12-24 hours after administration of a rituximab-containing product, including RITUXAN HYCELA. Administer aggressive intravenous hydration and anti-hyperuricemic therapy in patients at high risk for TLS. Correct electrolyte abnormalities, monitor renal function and fluid balance, and administer supportive care, including dialysis, as indicated

Infections

- Serious, including fatal, bacterial, fungal, and new or reactivated viral infections can occur during and following the completion of therapy with rituximab-containing products, including RITUXAN HYCELA. Discontinue RITUXAN HYCELA for serious infections and institute appropriate anti-infective therapy

Cardiovascular Adverse Reactions

- Cardiac adverse reactions, including ventricular fibrillation, myocardial infarction, and cardiogenic shock, may occur with rituximab-containing products, including RITUXAN HYCELA. Discontinue RITUXAN HYCELA for serious or life-threatening cardiac arrhythmias. Perform cardiac monitoring during and after all administrations of RITUXAN HYCELA for patients who develop clinically significant arrhythmias, or who have a history of arrhythmia or angina

Renal Toxicity

- Severe, including fatal, renal toxicity can occur after administration of rituximab-containing products, including RITUXAN HYCELA. Monitor closely for signs of renal failure and discontinue RITUXAN HYCELA in patients with a rising serum creatinine or oliguria

Bowel Obstruction and Perforation

- Abdominal pain, bowel obstruction, and perforation, in some cases leading to death, can occur in patients receiving rituximab-containing products, including RITUXAN HYCELA, in combination with chemotherapy

Immunization

- The safety of immunization with live viral vaccines following rituximab-containing products, including RITUXAN HYCELA, has not been studied and vaccination with live virus vaccines is not recommended before or during treatment

Embryo-Fetal Toxicity

- Based on human data, rituximab-containing products can cause fetal harm. Advise pregnant women of the risk to a fetus. Females of childbearing potential should use effective contraception while receiving RITUXAN HYCELA and for 12 months following the last dose of rituximab-containing products, including RITUXAN HYCELA

ADVERSE REACTIONS

- The most common adverse reactions (≥20%) of RITUXAN HYCELA observed in patients with FL in SABRINA were: infections, neutropenia, nausea, constipation, cough, and fatigue
- The most common adverse reactions (≥20%) of RITUXAN HYCELA observed in patients with DLBCL in MabEASE were: infections, neutropenia, alopecia, nausea, and anemia
- The most common adverse reactions (≥20%) of RITUXAN HYCELA observed in patients with CLL in part 2 of SAWYER were: infections, neutropenia, nausea, thrombocytopenia, pyrexia, vomiting, and injection site erythema

Please see the previous page and the accompanying full Prescribing Information, including **BOXED WARNINGS** and Medication Guide, for additional Important Safety Information.

Attention Healthcare Provider: Provide Medication Guide to patient prior to RITUXAN HYCELA treatment.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

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WE LOOK FORWARD TO YOUR PARTICIPATION

Minnesota, Vermont, and Federal Entities (eg, the Department of Defense and the Department of Veterans Affairs) have restrictions on receiving in-kind benefits (eg, meals, valet parking) at company-sponsored events. You are accountable for understanding such restrictions and complying with them. If you are licensed in or affiliated with any of these states or federal agencies, Genentech policies may restrict you from consuming any portion of the Genentech-sponsored meal at this program.

When you RSVP, please indicate whether you will accept or opt out of Genentech's in-kind benefits (eg, meals, valet parking) at the program. If you choose to opt out you may either pay for the meal and parking on your own, or not consume anything at the program. For all program attendees who receive Genentech's in-kind benefits at this program, Genentech will report the attendee's name and the value received as required by federal and state disclosure laws (for more information on the federal law please visit http://sunshine.gene.com). *The meal cost may vary by event location and be up to $125 per person (exceptions may apply).*

This is a Genentech promotional activity. Note: no continuing medical education (CME) credit will be awarded.

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