Project Livin' Label Video on fam-Trastuzumab Deruxtecan-nxki – The Backstory

Media: Enduring Material

Accredited Activity Release Date: December 4, 2023 Accredited Activity Expiration Date: December 4, 2026

Time to Complete Activity: 75 minutes

Activity Description

The FDA Oncology Center of Excellence (OCE), AACR and ONS are collaborating to launch a new educational initiative Project Livin' Label. The objective of these efforts is to educate the oncology community about select recent oncology drug approvals. The FDA will develop an educational video on a select recent oncology drug approval, discussing aspects found within the drug product label, such as safety findings and efficacy results. The FDA may choose to invite external guests to participate in the discussions. The FDA will share this video with AACR, along with the publicly available drug product label, and AACR will disseminate this information to the oncology community. Oncology practitioners can watch the video and review the associated drug product label and receive credit for this activity. All FDA oncology drug approvals have an approved package insert (US Prescribing Information). There is mixed use of the USPI depending on practice locations and type of practice. In addition, many practitioners are not familiar with the content of the USPI.

Target Audience

This educational initiative intends to educate the oncology practitioners on FDA's thinking behind an oncology drug approval, including discussions on the efficacy and safety findings from the registration trials. The discussions will center around the approval and reference relevant sections in the USPI where this information is located.

Educational Objectives

Upon completion of this activity, participants will be able to:

- Articulate the reasoning behind an FDA oncology drug approval.
- Identify the relevant sections of the drug USPI where information is located.
- Integrate this information into their clinical practice.

Accreditation Statement

The American Association for Cancer Research (AACR) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education activities for physicians.

Credit Designation Statement

AACR designates this enduring material for a maximum of 1.50 *AMA PRA Category 1 Credit(s)*TM. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The Oncology Nursing Society is accredited as a provider of nursing continuing professional development (NCPD) by the American Nurses Credentialing Center's Commission on Accreditation. Earn 1.50 contact hours of NCPD by watching the entire webinar recording, reading the accompanying product label, and completing an evaluation.

The Hematology/Oncology Pharmacy Association (HOPA) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. A statement of credit will be issued only upon completion of the post-activity evaluation form and post-test which can be accessed via this <u>page</u>.

Claiming CME Credit

Physicians and other health care professionals seeking *AMA PRA Category 1 Credit(s)*TM for this enduring continuing medical education activity must complete the online CME Request for Credit Survey. Certificates will only be issued to those who complete the survey. The Request for Credit Survey is available <u>here</u>. Your CME certificate will be sent to you via email after the completion of the activity.

MOC Statement

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 1.50 Medical Knowledge Maintenance of Certification (MOC) points in the American Board of Internal Medicine's (ABIM) MOC program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Participation information will be shared with ABIM through the ACCME's Program and Activity Reporting System (PARS).

Disclosure Statement

It is the policy of the AACR that the information presented at AACR CME activities will be unbiased and based on scientific evidence. To help participants make judgments about the presence of bias, AACR will provide information that Scientific Program Committee members and speakers have disclosed all financial relationships they have with ineligible companies whose primary business is producing, marketing, selling, reselling, or distributing healthcare products or services used by or on patients. All of the relevant financial relationships listed for these individuals have been mitigated.

Faculty Disclosures

Participant Name	Role	Financial Relationships	Туре
Asma Dilawari	Speaker	ReimagineCare Inc.	IC
Jennifer Gao	Program Committee	No Relationships	
Debora Geary	Speaker	No Relationships	
Kasey Hoggatt	Speaker	No Relationships	
Neha Mangini	Speaker	No Relationships	
Gerold Meinhardt	Speaker	Daiichi Sankyo, Daiichi Sankyo	E, S
Preeti Narayan	Program Committee, Speaker	No Relationships	
Naoto Ueno	Speaker	Carisma Therapeutics, Daiichi Sankyo Company LTD, Preferred Medicine, Bristol-Myers Squibb, Takeda Pharmaceutical Company, Limited, Kechow, Daiichi Sankyo Company LTD, DynaMed, Sysmex America, Inc., Gilead Sciences Inc, Chugai Pharmaceutical, Kyowa Hakko Kirin, Kirilys Therapeutics, Eisai, Phoenix Molecular Designs, Daiichi Sankyo Company, AstraZeneca, Gilead Sciences, Pfizer, Bayer, Cytodyne, Peptilogic, Medsir, Oncocyte	IC, IC, IC, IC, IC, IC, GC, IC,

Relationships are abbreviated as follows: E, Employment; FO, Fiduciary Officer; IC, Independent Contractor; S, Stock; SO, Stock Option; OS, Other Securities; OBO, Other Business Ownership; GC, Grant/Contract; T, Travel; GI, Gift; P, Patent; TM, Trademark, C, Copyright; OIP, Other Intellectual Property; O, Other.

Planning Committee Disclosures

FDA staff involved in the development and review of this activity have disclosed no relevant financial relationships.

AACR staff involved in the development and review of this activity have disclosed no relevant financial relationships.

ONS staff involved in the development and review of this activity have disclosed no relevant financial relationships.

Questions on CME or CE

For CME: Please contact the Office of CME at (215) 440-9300 or cme@aacr.org.

For NCPD: Please contact ONS at 866-257-4667 or help@ons.org.

For CPE: Please contact HOPA at 877-467-2791 or education@hoparx.org.