

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

Media: Enduring Material

Education Release Date: December 4, 2023

Time to Complete Activity: 90 minutes

Activity Description

The FDA Oncology Center of Excellence (OCE) and the AACR 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.

Disclosure Statement

It is the policy of the AACR that the information presented at AACR educational 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, re-selling, 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	Type
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, IC, IC, IC, IC, IC, IC, IC, IC, IC, IC, IC, IC, 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.

Questions on CE

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