Project Livin' Label video on osimertinib

Media: Online Education

Education Release Date: March 5, 2021 Time to Complete Activity: 90 minutes

Activity Description

The FDA Oncology Center of Excellence (OCE) and 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 about financial relationships they have with commercial entities that produce or market products or services related to the content of this educational activity.

Faculty Disclosures

Participant Name	Financial Relationships	Disclosure Types
Jill Feldman	No Relationships	
Roy Herbst	Junshi, Immunocore,	Advisor/Board Member;
	AbbVie, ARMO, AZ,	Consultant/Independent
	Biodesix, Bolt	Contractor; Grants/Research
	Biotherapeutics, BMS,	Support Recipient
	Candel, Cybrexa,	
	eFFECTOR, Lilly, EMD	
	Serono, Genentech/Roche,	
	Genmab, Halozyme, Heat,	
	I-Mab, Infinity, Loxo,	
	Merck, Mirati, Nektar,	
	Neon, NextCure, Novartis,	
	Oncternal, Pfizer, Ribbon,	
	Sanofi, Seattle Genetics,	
	Shire, Spectrum, STCube,	
	Symphogen, Takeda,	
	Tesaro, Tocagen,	
	WindMIL, Xencor	
Richard Pazdur	No Relationships	
Yuri Rukazenkov	AstraZeneca	Full-time/part-time Employee
Harpreet Singh	No Relationships	

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.