

Project Livin' Label Video on Ivosidenib – The Backstory

Media: Online Education

Education Release Date: July 12, 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 their financial relationships 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 for these individuals have been mitigated.

Faculty Disclosures

Participant Name	Role	Financial Relationships	Type
Stephane de Botton	Speaker	Pfizer, AbbVie Inc., Servier Pharmaceuticals LLC, Bristol-Myers Squibb, Agios Pharmaceuticals, Inc., Astellas Pharma, forma therapeutics, Jazz Pharmaceuticals Inc., Celgene Corporation, syros pharmaceuticals	IC, IC, IC, IC, IC, IC, GC, IC, IC, IC
Amir Fathi	Speaker	Immunogen, Bristol-Myers Squibb, Genentech, Massachusetts General Hospital, Celgene, Kite Pharma, Inc., Orum, Kura Oncology, AbbVie, Takeda Oncology, Forma, Menarini Group, Amgen, AbbVie, EnClear, Mablyitics, Pfizer, Novartis, Servier Pharmaceuticals LLC, PureTech, Remix, Autolus, Gilead Sciences Inc, Servier Pharmaceuticals LLC, Daiichi Sankyo Company, Bristol-Myers Squibb, Ipsen Biopharmaceuticals, Inc, Astellas Pharma, Rigel Pharmaceuticals, Inc.	IC, IC, IC, E, IC, IC, IC, IC, GC, IC, IC, IC, IC, IC, IC, IC, IC, IC, IC, GC, IC, GC, IC, IC, IC
Jennifer Gao	Program Committe	No Relationships	
Lucille Giunta	Speaker	No Relationships	
Matthew Newman	Speaker	No Relationships	
Kelly Norsworthy	Moderator	No Relationships	
Susan Pandya	Speaker	Servier Pharmaceuticals LLC, Servier Pharmaceuticals LLC	E, E
Aura Ramos	Speaker	No Relationships	
Ashley Woods	Speaker	No Relationships	

Relationships are abbreviated as follows: E, Employee of listed company, G, Grant/research support recipient, A, Advisor or review panel member, C, Consultant, S, Stock Shareholder, SB, Speakers' Bureau, H, Honoraria, 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

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