Cancerworld

More evidence-based info on off-patent oncology drugs

Editorial Staff / 2 March 2020

The American Association for Cancer Research (AACR) has offered help to the U.S. Food and Drug Administration (FDA) on its ambitious Project Renewal, that aims to evaluate accumulated scientific evidence on safety and efficacy of long-standing off-patent oncology drugs, so to update labeling information.

Over time, drug labeling becomes outdated as new information becomes available in the post-

marketing setting, so the FDA decided in 2018 to launch Project Renewal to keep generic oncology product labeling up to date on a more frequent basis. In its first year, Project Renewal has developed a set of repeatable processes and procedures to evaluate evidence from published literature to inform regulatory decisions for updated product labeling of older oncology drugs, according to a joint announcement release by AACR and FDA.

“Patients and health care providers rely on accurate medical product labeling to inform care and treatment decisions.” said Richard Pazdur, MD, director of the FDA’s Oncology Center of Excellence. “We are pleased that the American Association for Cancer Research is joining Project Renewal, highlighting our goal to add value to the labeling update process by engaging the oncology community, generating awareness of the importance of FDA product labeling, and creating educational opportunities for clinical and basic cancer scientists as well as oncology fellows to learn how the FDA reviews evidence that informs product labeling.”

“The AACR is very proud to work with the FDA on this exciting project that has the potential to help oncologists in their decision making and, most importantly, to guide treatment decisions based on scientific evidence for the benefit of cancer patients,” said Margaret Foti, PhD, MD (hc), chief executive officer of the AACR.

The key goals of Project Renewal

- Develop repeatable processes
- Use published data
- Engage with oncology community
- Foster educational experiences