

# Author's Accepted Manuscript

## Looking to the Future in an Unprecedented Time for Cancer Drug Development

Paul G. Kluetz, Richard Pazdur



[www.elsevier.de/ending](http://www.elsevier.de/ending)

PII: S0093-7754(16)00002-6  
DOI: <http://dx.doi.org/10.1053/j.seminoncol.2016.01.001>  
Reference: YSONC51900

To appear in: *Semin Oncol*

Cite this article as: Paul G. Kluetz, Richard Pazdur, Looking to the Future in an Unprecedented Time for Cancer Drug Development, *Semin Oncol*, <http://dx.doi.org/10.1053/j.seminoncol.2016.01.001>

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting galley proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Looking to the future in an unprecedented time for cancer drug development

Paul G. Kluetz and Richard Pazdur

Office of Hematology and Oncology Products

FDA/CDER/OND

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

Paul.Kluetz@fda.hhs.gov

Over the past several years sustained commitment to cancer research has been translated into therapeutic advances across a broad range of drug and biologic products. The magnitude of benefit observed with many of these cancer therapies has enabled the Office of Hematology and Oncology Products at the FDA to proactively utilize regulatory programs to expedite the delivery of safe and effective therapies to patients. How did we get here, and what can the cancer drug development community do to continue to bring tangible benefit to cancer patients?

In 2001 investigators published results of imatinib, an oral therapy that resulted in 53 of 54 interferon-refractory chronic myelogenous leukemia patients achieving durable complete hematologic response. The authors concluded their manuscript with the prescient statement that their results "demonstrate the potential for the development of anticancer drugs based on the specific molecular abnormality present in human cancer".<sup>1</sup> This marked a beginning for rationally developed cancer drugs based on identification and targeting of oncogenic pathways driving tumor growth, and we continue to see impressive durable response rates with other therapies directed at mutations across a range of targets and histologies.

Download English Version:

<https://daneshyari.com/en/article/10924285>

Download Persian Version:

<https://daneshyari.com/article/10924285>

[Daneshyari.com](https://daneshyari.com)