Prostate Cancer: Score One for Validated Targets

This CCR Focus went to press shortly after the Food and Drug Administration (FDA) approval, on April 28, 2011, of abiraterone in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer. Abiraterone was synthesized in the early 1990s by Mike Jarman’s group at the Institute of Cancer Research, Sutton, Surrey, England. After some delay, clinical development was initiated under the leadership of Johann de Bono, who conducted phase I, II, and III trials, with activity observed at each stage. Several aspects of this are notable. One, this is the third major regulatory approval in the space of 1 year for a disease that once had few treatment options after testosterone-lowering therapy. Second, approvals of all 3 were based on an overall survival advantage, a feat that many have argued has become impossible in oncology. Third, the approvals were for drugs against old targets, microtubules and the androgen receptor, and in the case of sipuleucel-T, a new approach in an established treatment paradigm (i.e., immunotherapy). The irony of this should not be lost in the age of targeted therapies, with the steady expansion of exotic new targets as well as the exhaustive list of kinase inhibitors/antiangiogenic agents in development. Taken together, these studies represent the type of achievement that shows oncology at its best—incremental steps that instruct us in the biology of cancer while providing true clinical benefit. The clinical trial results clearly meet the “substantial evidence” criteria of adequate and well-controlled investigations anticipated when the U.S. Congress adopted the 1962 Drug Amendments requiring “manufacturers of drug products to establish a drug’s effectiveness by substantial evidence” (1, 2). It is fitting that de Bono and Gerhardt Attard, who also participated in abiraterone development, serve as Guest Editors of this issue of CCR Focus. They have recruited a series of experts to discuss the new developments: Massard and Fizazi to discuss continued androgen receptor signaling; Madan, Pal, Sartor, and Dahut to discuss cabazitaxel and other small molecules in development; and Gulley and Drake to discuss sipuleucel-T and other immunotherapies. These articles are complemented by a discussion by Danila, Fleisher, and Scher of circulating tumor cells as biomarkers, also the subject of an FDA device approval in 2009. As with every issue of CCR Focus, this issue is meant to be accessible to those interested but nonexpert in this topic, to stimulate the thinking of those working in the field, and to highlight concepts for future research.

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References


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