Cancer Immunotherapy: Chapter 13. Pharmacokinetics and Safety Assessment

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To effectively exploit novel pharmacologic targets in oncology, drug leads must be translated through an intense, iterative process involving progressive improvement in multiple qualities, ultimately yielding registered pharmaceutical agents. The challenges of juggling multiple, sometimes mutually antagonistic qualities can be difficult, but in this chapter is illustrated by approaches that have proven effective historically. Ideal or highly optimized pharmacokinetics, pharmacodynamics and safety are properties essential to the success of a new therapy within a specific indication. The goal of general pharmacokinetic investigation in drug discovery is to identify a drug candidate with properties that allow delivery and exposure to the target molecule for a sufficient duration of time so as to confer the desired pharmacologic activity. The adequate exposure of the candidate to the target or target occupancy must be defined in efficacy studies and is frequently characterized by concentration and duration, such as area under the concentration versus time curve (AUC) or time above a defined concentration (i.e., time above IC50). The ability of a candidate to achieve adequate exposure is dependent upon its pharmacokinetic properties, which include absorption (including exclusion by enteric or brain transporters and innate permeability), distribution (including target receptor occupancy, concentration in certain tissues), metabolism (liver, kidney, intestine and other tissues), and excretion, collectively referred to as the ADME properties of a drug candidate. The candidate must also have an acceptable safety profile relative to the potential benefit of treatment. Safety concerns for oncologic agents are frequently related to the mechanism of activity, so unfortunately they often track with efficacy, but they can also be related to off-target effects, such as nonselectivity or metabolite activity. Engineering a qualified drug candidate with the appropriate and balanced pharmacokinetic, pharmacodynamic, and safety properties rarely occurs by happenstance, although one must be able to recognize and exploit serendipitous success in this field. For small molecule drug candidates, these qualities are engineered by way of optimization and multiple structure-activity and structure-liability response iterations, involving the integrated activities of pharmaceutical medicinal chemists, pharmacokineticists and toxicologists.

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