Biodefense is focused on providing protection against biological weapons, both for the military and for the broader civilian population. Biological weapons may include toxins, infectious agents and radiation. Some of these may be built similar to common chemical or nuclear weapons, and thus may be challenging to distinguish from other threats.

Ricin, a plant toxin capable of being weaponized, has well documented toxicity. It is known to be lethal by the aerosol route, with a median lethal dose of 0.1-1 µg/kg. Ricin has a single active site and toxicology studies have demonstrated consistency across species in a manner predictive of human disease. The active site in purple, the A chain irreversibly inhibits the ribosome, prohibiting protein synthesis.

RESULTS

Biodefense indications generally meet the definition of Orphan Diseases and are eligible for Orphan and Fast Track designations. These studies form the initial basis for the development and advancement to pivotal studies and human efficacy trials. We discuss some of the key requirements to pursuing FDA approval.

Biodefense applications represent orphan populations and approvals for radiometric countermeasures usually involve pursuit of marketing approval via the "Animal Rule" under the novel, thermostabilized ricin toxin vaccine, RiVax. We discuss some of the key requirements to pursuing FDA approval.

In mice, a linear epitope (aa 97-108) defined by Mabs PB10/R70 is immunodominant. The Animal Rule and has shown:

The Animal Rule is applicable where:

- Human efficacy studies are not ethical (e.g., exposing humans to bioterrorism agent).
- Clinical trials are not feasible (e.g., field trials after an accelerated release are not possible).

The Animal Rule is generally applicable to biodefense threats, especially ricin and other unstable biological agents.

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