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**ETI-204 Provides a Dramatic Improvement in Survival at the Onset of Active Anthrax Disease and is Well Tolerated in Nonhuman Primates**

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*Abstract:*

**Background:**

ETI-204 (Anthim) is an affinity-enhanced deimmunized humanized mAb that neutralizes anthrax toxin Protective Antigen (PA) by targeting its cell receptor-binding domain. Anthim is being developed for the treatment of inhalational anthrax; it was previously shown to be highly effective (when administered IV or IM) in a post-exposure prophylaxis regiment in rabbits. Here we present results from two studies with the following goals: 1) evaluate the efficacy of Anthim in a post-exposure prophylaxis primate model and 2) further explore safety of this antibody.

**Methods:**

Cynomolgus macaques were challenged with aerosolized *B. anthracis* (Ames) spores (200 LD<sub>50</sub>). Anthim was administered as a single IV (2 different doses) or IM (2 different doses) injection 24 hours post-challenge. Control animals were treated with saline. Animals were observed for clinical signs and survival. Laboratory evaluations were performed. A separate safety study was performed to evaluate tolerability, immunogenicity, PK, cardiovascular, hematology and clinical chemistry parameters at multiple time points, as well as gross necropsy.

**Results:**

The appearance of diagnostic indicators was noted 24h post-challenge (immediately before treatment). Anthim provided substantial protection when administered IV (up to 67% survival) or IM (up to 75% survival) with doses as low as 4 mg/kg showing excellent efficacy compared to

animals treated with saline alone. In addition, Anthim was extremely well tolerated and no significant side effects were observed at doses as high as ~8 fold more than the effective dose.

**Conclusions:**

These studies demonstrate that a single dose of Anthim administered either IV or IM is a very potent, effective, and safe treatment of active anthrax disease in non-human primates.

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