Questions for the Committee

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- The Applicant has conducted a clinical trial to evaluate the efficacy of sugammadex to effect the "Immediate Reversal" of neuromuscular blockade (NMB). The primary efficacy endpoint was the time from start of administration of rocuronium bromide (RCB) or succinylcholine (Sux) to the recovery of T1 to 10% if its baseline value. Sugammadex was administered to patients 3 minutes following administration of RCB.
  - Does the primary endpoint have clinical relevance? If no, what other endpoints might be more useful?
  - Based on the data submitted from this study, is there sufficient clinical information to assess whether sugammadex, when used with RCB, provides a clear advantage when confronted with a "cannot ventilate/cannot intubate" situation in the clinical setting? If not, what additional information would be required to assess a possible role for sugammadex in this scenario?

Questions for the Committee

- Based on the nonclinical data submitted by the applicant from the sugammadex distribution, juvenile animal, reproductive toxicology, and dedicated bone studies:
  - Has the risk for adult patients, including patients with fractures or surgical injury to bone been adequately characterized?
  - Has the risk for pediatric patients been adequately characterized?
  - Does the nonclinical data support the safety of sugammadex for clinical trials in a pediatric population?
  - If the answers to any of the above questions is “no,” what additional information is required to support the use of sugammadex in these populations?

Questions for the Committee

- **Has the applicant adequately demonstrated that sugammadex:**
  - **reverses neuromuscular blockade from rocuronium and vecuronium;**
  - **immediately reverses neuromuscular blockade from rocuronium?**
  - **can be used safely in the targeted population? Please discuss potential hypersensitivities in this population, if patients at risk can not be identified.**