

## Rabies Antibody Cocktail Gets Fast Tracked

**FDA grants fast-track status to antibody cocktail to help prevent rabies in humans after exposure.**

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The U.S. Food and Drug Administration's Department of Health and Human Services recently granted a "fast track" designation to the Dutch biotechnology company Crucell N.V.'s rabies monoclonal antibody cocktail.

The status, which is reserved for drugs that are intended to treat serious or life-threatening diseases and that demonstrate the potential to address unmet medical needs, is expected to facilitate the development and expedite the review process of the drug.

The company is developing the cocktail to help prevent rabies in humans after exposure.

"We are very pleased to receive the fast track designation for our rabies antibody cocktail," said Jaap Goudsmit, MD, Ph.D., Crucell's chief scientific officer. "Given the unmet medical mechanisms clearly signal the importance of expanding rabies treatment availability. People deserve to be protected against rabies."

Phase I of the study indicates that the cocktail is well tolerated, that it provides the expected neutralizing activity and that it can be safely co-administered in combination with a standard rabies vaccine.

A second phase-I study to assess the safety and efficacy of the antibody is still underway.

Based on market needs, Crucell predicts that peak sales for its cocktail will exceed \$300 million.