BLA REGULATORY

PHARMAFOCUS

Weekly Newsletter - One Topic at a Time

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About Us

BLA Regulatory is located in the State of Maryland, conveniently close to the FDA's headquarters. We offer U.S. agent services for all types of FDA-regulated products, including drugs, cosmetics, medical devices, and more. Our team can guide you through the entire application and registration process to ensure FDA compliance. Please visit our office website for more information or if you need any assistance.

Potential waives of phase 1 studies in Japanese prior to join global clinical trials for drugs that had early clinical data outside Japan

PMDA Notification No. 1225 (2), dated December 25, 2023).

PMDA has mentioned in this Notification that based on risks and effects of ethnic factors, it is possible to waive phase 1 studies in Japanese prior to join global multi-regional clinical trials (MRCTs) for drugs that had early clinical studies outside Japan if meeting following conditions.

1. Safety of study drug

- The results of non-clinical studies suggest no significant risk with an unclear mechanism of onset at the dose used in the MRCT(s).
- The maximum dose used in MRCT(s) has a sufficient safety margin,and no significant risks have been identified in early foreign clinical trial(s).
- There are clear approaches and monitoring methods for mitigating potential risks and the potential risks are manageable in the MRCT(s).
- When there are similar drugs (e.g., the same API, the same MOA, biosimilars, etc.) which can be used as a reference in the safety evaluation, no clinically significant risk of the study drug is anticipated.

2. Effect of ethnic factors on study drug:

- The PK of the study drug is linear.
- The drug is poorly metabolized or multiple metabolic pathways are involved.
- It has not been reported that there are ethnic differences in the genetic polymorphisms of metabolic enzymes or transporters involved, or that the prevalence of polymorphisms with increased blood concentration of the study drug is higher in Japanese than in non-Japanese.
- The drug has characteristics that make the safety and PK unlikely to be affected by ethnic factors (like poorly into systemic but act locally)
- There is no significant impact of ethnic factors like race, region, body weight on safety or PK based on previous trial(s) in multiple regions.

3. Additional measures can be taken to ensure the safety

- Set up a cohort to evaluate the safety of a small number of Japanese participants with appropriate intervals (e.g., one participant at a time) prior to the main part of the MRCT(s).
- Increase the frequency of visits and monitoring during the early stage of administration.
- During the initial stage, Japanese participants will either be hospitalized or observed at the study site for a certain period.

PMDA Washington D.C. Office

PMDA Washington D.C. Office has been established in Washington, D.C. as the first PMDA's U.S. office, dated November 1, 2024.

The DC office will promote enhancement of regulatory cooperation and information exchange on regulations with administrative organizations in the U.S., including the U.S. Food and Drug Administration (FDA) on site. And for start-ups which locate in the U.S., the office will provide the information regarding Japanese regulations on reviews and post-marketing safety measures, as well as offer the services including early general development consultation and related services.

The official logo of PMDA has been renewed

Both logos will be used for the time being during the transition period.

Old

Pmda 独立行政法人 医薬品医療機器総合機構 Pharmaceuticals and Medical Devices Agency

New

PMDA

PMDA believes that these measures will support to promote the development of innovative drugs and medical devices in Japan, contributing to making everyone's lives brighter together.

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