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LETTER

# Teneligliptin and "Thorough QTc study": thorough enough?

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## Dear editor

I read with interest the "Thorough QTc study" with teneligliptin by Erande et al[1]. It came as a surprise to me that the basic structure required to conduct such a trial as per the ICH E14 recommendations for the industry was not followed.[2] The recommended design to conduct such a trial was not universally followed (Table1).

The original thorough QT/QTc study was conducted by the recommending authority (PMDA) in Japan using a dose range of 40 mg (therapeutic dose) and 160 mg (experimental dose) for teneligliptin compared to moxifloxacin 400 mg (active control dose).[3] The upper limit of 90% CI was more than 10 ms for the 160 mg dose in both sexes. More than 10 ms CI was also documented in females with the 40 mg dose, prompting the Japanese authorities to include this adverse event as a warning.

In view of the above-mentioned deficiency in the study design as well as reporting strategy, the data analyzed in the Erande et al, study can be considered as an effect of teneligliptin on QT interval and not a thorough QTc study.

I would be obliged if the following issues were adequately clarified with your involvement.

**Table 1** Requirements for a thorough QT/QTc study[2]

| Recommended criteria | Erande et al, design[1] |
|---|---|
| • Randomized, placebo-controlled trial | • Open-labeled, non-placebo-controlled trial |
| • Requirement for active control arm (moxifloxacin) | • No active-controlled arm included |
| • The selected dose: 8–10 times the therapeutic dose | • Only therapeutic dose was used |
| • QTc calculated by Fridericia's or Bazett's correction | • QTc calculated by Bazett's correction |
| • QTc reporting: maximum difference with two-sided 90% confidence interval (CI). The upper level of 90% CI crossing 10 millisecond (ms) was considered as abnormal. | • QTc reporting: Mean ± SD |

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## Disclosure

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